

SMG 1251.10

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF MANAGEMENT

Effective Date: November 4, 2016

1. OFFICE OF MANAGEMENT (DKKWK).

- A. Advises the Center Director regarding all administrative management matters.
- B. Represents the Center for Devices and Radiological Health (CDRH) on all administrative management matters in interactions with the Department and Agency.
- C. Plans, develops, and implements Center management policies and programs concerning financial and human resource management, contracts and grants management, organizational, and general administrative support services.
- D. Develops and implements the Center's long-range and operational plans.
- E. Develops and implements new strategies for emerging problems and new management initiatives.
- F. Develops and applies evaluation techniques to measure the effectiveness of Center programs.
- G. Analyzes and evaluates the effectiveness of the Center's overall acquired and planned contracting program operations in meeting established goals and objectives ensuring Center adherence to contract and grant regulations.
- H. Monitors the development and operation of planning and financial systems for Center activities and resource allocations and advises the Center Director on corresponding policies and guidelines.

- I. Directs Center organizational and management programs.
- J. Initiates and manages studies designed to improve processes, resource allocations, policy review and oversight in the Center.

2. PLANNING AND PROGRAM ANALYSIS STAFF (DKKWK1).

- A. Provides program and project management support and coordination for Center- wide and Office of Management (OM) administrative initiatives.
- B. Facilitates the OM strategic planning and prioritization processes.
- C. Promotes and lead continuous improvement initiatives across OM; conducts analysis or studies to support Business Process Improvement.
- D. Leads OM metrics development, tracking, and analyses against stated performance targets and goals.
- E. Facilitates and tracks the Office of Management (OM) Customer Service initiative as well as OM Quality Management.
- F. Assesses OM organizational structure functionality, roles/responsibilities, performance measurement and reporting.
- G. Establishes OM governance processes and mechanisms that enable alignment with mission and goals.
- H. Facilitates the OM communications program, including the coordination of internal/external communications for the OM.

3. ACQUISITIONS AND GRANTS SERVICES STAFF (DKKWK2).

- A. Oversees CDRH's acquisitions planning and provides assistance, advice, review, analysis and problem-solving for new, existing, anticipated, or impending acquisitions, contracts, Inter Agency Agreements and grants.
- B. Serves as Center Liaison between the Agency's Office of Acquisitions and Grants Services (OAGS) and CDRH Programs related to all acquisition Management activities.
- C. Serves as the Center Contracting Officers Representative (COR) Acquisition Development Program, Liaison for Center IAA and Grants oversight, Small Business Acquisition Program, Center Ratifications/Procurement Program, Center Acquisition Internal Audit Program, Acquisition Compliance and Policy Program, Small purchase program.

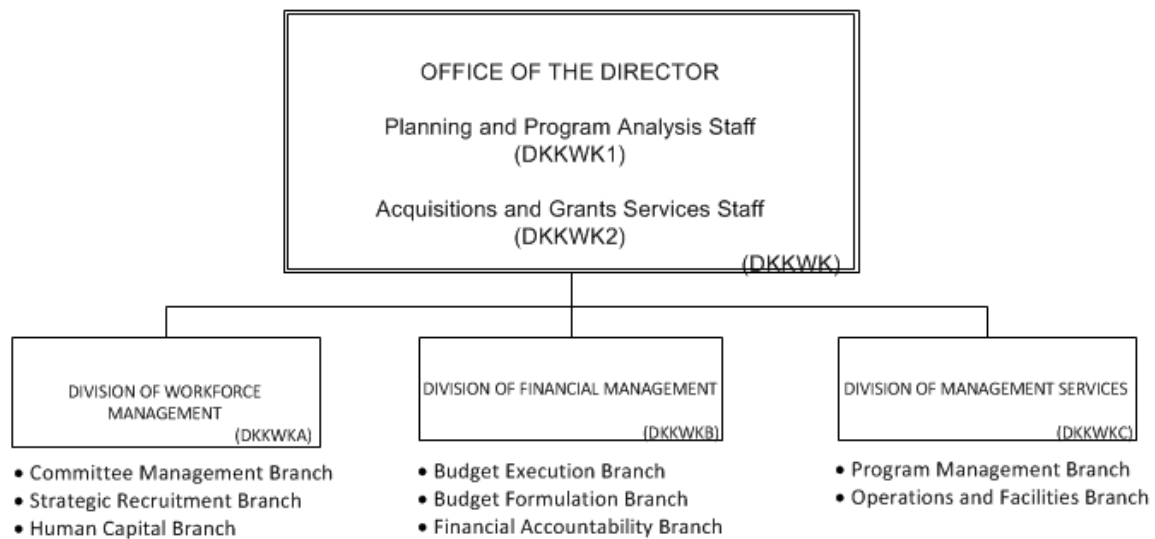
- D. Coordinates all FDA OAGS Advance Acquisition Planning/ Acquisitions within CDRH.
- E. Provides guidance and assistance on new and/or amended acquisition law, regulations, requirements and policies to include professional certification requirements for the Center Contracting Officer Representatives acquisition community.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Director, Center for Device and Radiological Health on July 28, 2016, and effective on November 4, 2016.

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STAFF MANUAL GUIDE 1251.10
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: November 4, 2016

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKWK):

- Planning and Program Analysis Staff (DKKWK1)
- Acquisitions and Grants Services Staff (DKKWK2)

DIVISION OF WORKFORCE MANAGEMENT (DKKWKA)

- Committee Management Branch
- Strategic Recruitment Branch
- Human Capital Branch

DIVISION OF FINANCIAL MANAGEMENT (DKKWKB)

- Budget Execution Branch
- Budget Formulation Branch
- Financial Accountability Branch

DIVISION OF MANAGEMENT SERVICES (DKKWKC)

- Program Management Branch
- Operations and Facilities Branch