

SMG 1257.7

**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 IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH

DIVISION OF PROGRAM OPERATIONS AND MANAGEMENT

Effective Date: 09/25/2012

1. DIVISION OF PROGRAM OPERATIONS AND MANAGEMENT (DKKWJE).

- A. Develops and interprets policy guidance in response to specific requests from the medical device and electronic products industries, trade associations, other Federal agencies, other countries, congress, State agencies, and the general public.
- B. Conducts management and program analysis studies and participates in the program planning process to identify operational goals and evaluation methods. Designs and recommends systems and procedures and develops policy recommendation to implement study conclusions.
- C. Develops policies and coordinates cross-cutting pre and postmarket activities to improve efficiencies within and between the Office and other offices.
- D. Coordinates activities on classification actions, petitions, appeals, 510(k)s, Humanitarian Device Exemptions (HDEs), premarket approval applications (PMAs), product development protocols (PDPs), investigational device exemptions (IDEs), third party review and Clinical Laboratory Improvement Amendment (CLIA) with Center and Agency components or other organizations.
- E. Provides authoritative advice and guidance to the Office Director on management policies, guidelines, issues and concerns that impact Office/Center programs and initiatives.
- F. Advises the Office Director regarding all administrative management matters.

- G. Provides leadership, guidance and directs the development of long-range strategic management and operational plans, and systems for Office activities and directs technical support.
- H. Provides all Human Resources services including Capital HR, appointment mechanisms, recruitment flexibilities, SES appointments, Title 42 appointments, retention flexibilities and position management.
- I. Administers and executes the Office's management and fiscal planning and performance activities, budget formulation and execution, payroll, accounting and property management.
- J. Conducts payroll, operating, and user fee analysis and forecasting of resources.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs on September 25, 2012.

Staff Manual Guide 1257.7
Organizations and Functions
Effective Date: September 25, 2012

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STAFF MANUAL GUIDE 1257.7
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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Division of Program Operations and Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR