

SMG 1117A.64

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Finance, Budget, Acquisitions, and Planning

Office of Planning, Evaluation, and Risk Management

Effective: February 9, 2022

1. Office of Planning, Evaluation, and Risk Management (DCNED).

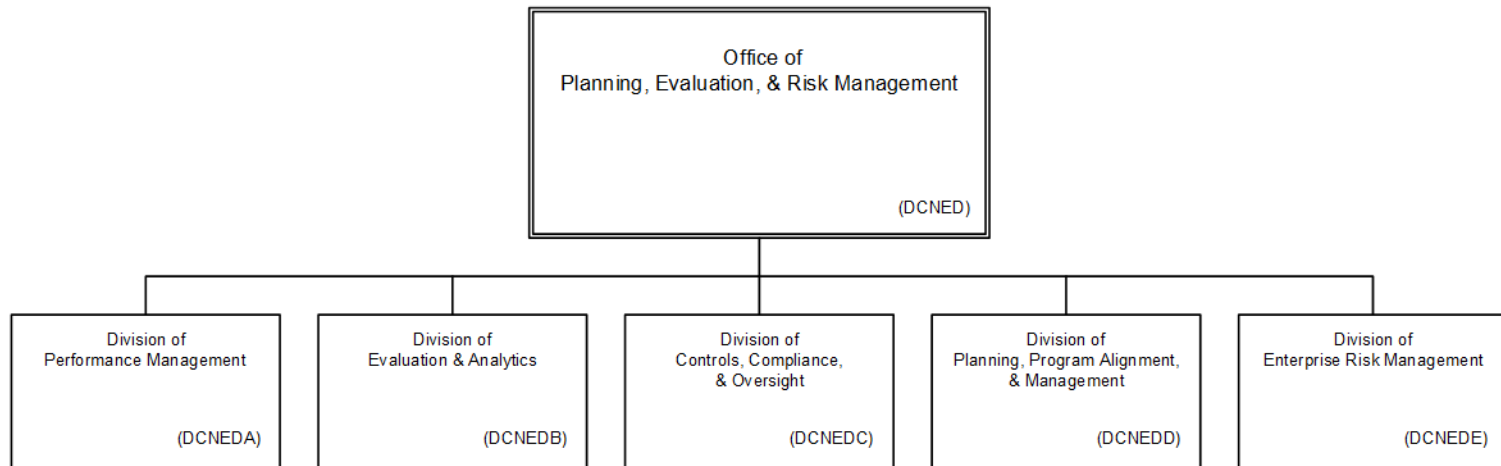
- A. Leads FDA-wide strategic planning initiatives.
- B. Leads FDA-wide risk response and risk management initiatives.
- C. Advises and assists the Commissioner and other key FDA officials concerning the performance of FDA planning, evaluation, internal controls, risk management and process improvement activities.
- D. Develops program and planning strategy through analysis and evaluation of issues affecting program operations and performance.
- E. Leads the FDA Strategic Planning Council.
- F. Leads the FDA Enterprise Risk Management Council.
- G. Leads the Senior Assessment Team.
- H. Consults with and supports the FDA preparation of legislative proposals, budget proposals, and technical assistance to Congress
- I. Develops FDA's evaluation programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.
- J. Estimates marginal impact of funding changes on FDA performance and ability to promote public health.
- K. Leads effort to analyze FDA business processes for improvement and automation.
- L. Coordinates the development of public health and program outcome measures and monitors and reports on the status of those measures. Develops logic models that link FDA activities and outputs to outcomes.

- M. Coordinates and performs user fee program evaluation and analysis. Leads and coordinate various user fee program initiatives related to [performance improvement, program management, and quality systems studies.
- N. Oversees FDA's compliance with the Federal Managers Financial Integrity Act (FMFIA) of 1982 and OMB Circular No. A-123 (Management's Responsibility for Enterprise Risk Management and Internal Control.
- O. Performs and coordinates analytics projects and programs.
- P. Supports and performs descriptive, prescriptive, exploratory, and predictive analytics projects at the FDA and organizational component levels.
- Q. Provides analytics-related subject matter expertise and support such as examples, case studies, and training to other FDA groups performing analytics projects.
- R. Develops and implements governance for data-related and analytics-related processes in collaboration with FDA offices.
- S. Assists with the design and development of data analyses to support business decisions, including data visualizations and recommendations for appropriate display and analytics technologies.
- T. Supports the development of data source documentation as needed for valid and verifiable data analyses.
- U. Manages and coordinates reorganization program activities, competitive sourcing, and delegations of authority program activities for FDA.
- V. Administers FDA's Standard Administrative Code (SAC) system for organizational components.

2. Authority and Effective Date.

The functional statements for the Office of Planning, Evaluation, and Risk Management were approved by the Acting Commissioner of Food and Drugs on December 7, 2021, and effective on February 9, 2022.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Operations, Office of Finance, Budget, Acquisitions, and Planning, Office of Planning, Evaluation, and Risk Management organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Planning, Evaluation, and Risk Management (DCNED):
Division of Performance Management (DCNEDA)
Division of Evaluation and Analytics (DCNEDB)
Division of Controls, Compliance, and Oversight (DCNEDC)
Division of Planning, Program Alignment, and Management (DCNEDD)
Division of Enterprise Risk Management (DCNEDE)