

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Planning, Evaluation, and Risk Management

Effective Date: May 13, 2024

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

- 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, risk management and process improvement activities.
- D. Advises programmatic and planning strategies through analysis and evaluation of issues affecting program operations and organizational performance.
- E. Develops FDA's evaluation programs to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.
- F. Leads the FDA Strategic Planning Council.
- G. Leads the FDA Enterprise Risk Management Council.
- H. Consults with and supports the FDA preparation of legislative proposals, budget proposals, and technical assistance to Congress.
- I. In coordination with OFBA and other FDA components, assesses marginal impact of funding changes on FDA organizational performance and ability to promote public health.
- J. In collaboration with other FDA components, analyzes business processes and conducts process improvement and automation.

- K. Coordinates the development of public health and program outcome measures to ensure outcomes support FDA's mission, organizational strategy, and appropriations. Ensures monitoring and reporting of those measures provides a feedback loop for evaluations and strategy refinements. Develops logic models that link FDA activities and outputs to outcomes.
- L. 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.
- M. 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).
- N. Provides process facilitation expertise to FDA components (i.e., to support consensus sessions with internal and external stakeholders).

2. Administrative Staff (DCAG1).

- A. Plans, develops, and implements a wide range of administrative management activities for the office including financial, human capital, and other essential administrative support services, in coordination with office subcomponents.
- B. Represents the office and serves as a liaison on administrative management matters.
- C. Provides support to plan, develop, and edit various materials and work products including evaluations/assessments, reports, presentations, and correspondences for clarity and accuracy.
- D. Provides 508 compliance support to office to ensure work products meet requirements.
- E. Analyzes functional and technical requirements of proposed or existing IT support to determine pathways and provide necessary support to meet mission objectives.
- F. Conducts special projects and assignments in support of office priorities and management initiatives.

3. Strategic Planning and Change Management Staff (DCAG2).

- A. Develops, implements, and monitors FDA wide strategic planning including long-term strategic plans, strategic action plans, risk response, and implementation plans in alignment with the DHHS strategic plan, and other DHHS organizations. Advises FDA senior leadership and organizations to respond to a dynamic public health landscape.

- B. Leads the development of FDA's organizational performance plans and strategic priorities.
- C. Provides direction and council to senior FDA leaders for the development of long-term plans and strategies.
- D. Leads, performs, and coordinates FDA's organizational change management function. Assists programs to solve critical transformation challenges by applying evidence-based best practices to support adoption of an organization's vision, mission, as well as strategic goals and objectives.
- E. Leads and coordinates activities to support the FDA Strategic Planning Council.

4. Evaluation and Analytics Staff (DCAG3).

- A. Leads, performs, and coordinates the FDA's program evaluation function.
- B. Performs FDA program and policy evaluations and analytical studies. In coordination with OFBA, recommends alternative courses of action to increase effectiveness of FDA allocation of resources and to improve program and project performance.
- C. Performs analyses of significantly broad FDA issues identified in the planning process. Recommends and/or implements steps to resolve these issues.
- D. Coordinates information gathering and reporting for the FDA's annual Evaluation Plan; coordinates the annual Evaluation Plan with DHHS.
- E. Conducts special evaluation and analytical studies in support of FDA policy development and in resolution of broad FDA issues.
- F. Evaluates the impact of FDA operations and policies on regulated industries and other FDA constituents, and external factors on FDA programs.
- G. Assists and consults with FDA components on the design and execution of key program and process re-design; and scientific review components to enhance transparency, consistency, accountability, and continuous improvement of review processes.
- H. Performs and coordinates analytics projects and programs.
- I. Supports and performs descriptive, prescriptive, exploratory, and predictive analytics projects at the FDA and organizational component levels.
- J. Provides analytics-related subject matter expertise and support such as examples, case studies, program evaluation, and training to other FDA groups performing analytics projects.

- K. Develops and implements governance for data-related and analytics-related processes in collaboration with FDA offices and or DHHS.
- L. Assists with the design and development of data analyses to support business decisions, including data visualizations and recommendations for appropriate display and analytics technologies.
- M. Provides business process design, operations analysis, modeling, and analysis services to FDA programs and initiatives.
- N. Prioritizes program, project, and evaluation requirements based on criteria such as risk and available resources.
- O. Facilitates cross-organizational sharing of key program and process improvements. Aids evaluated organizations address areas identified as needing improvement.

5. Enterprise Risk Management Staff (DCAG4).

- A. In alignment with and under direction from FDA executive leadership, Develops, implements, and oversees the enterprise risk management program including the processes for identifying, assessing, prioritizing, mitigating, monitoring, and reporting on key risks that could impair the agency's ability to achieve its mission or goals.
- B. Collaborates with leadership of FDA components to promote effective governance of significant enterprise risks.
- C. Advises and informs FDA components, and leaders on risk management matters, as well as promotes the consideration of risk management factors in budgetary, operational, and strategic decision-making.
- D. Oversees enterprise risks by FDA components in compliance with the Federal Managers Financial Integrity Act (FMFIA) and OMB Circular No. A-123 (Management's Responsibility for Enterprise Risk Management and Internal Controls).
- E. Monitors and reports on FDA's progress in taking timely and appropriate corrective action to address recommendations identified on the FDA Risk Register/Profile.

6. Performance Management Staff (DCAG5).

- A. Leads and aligns the FDA short- and long-range performance planning objectives and processes.
- B. Performs and or coordinates program advisory, planning, and analysis services as well as the FDA's performance management functions with the

Department of Health and Human Services (DHHS), internal and external stakeholders.

- C. Represents the FDA for DHHS and Office of Management and Budget (OMB) performance planning reporting and related activities.
- D. Creates and provides performance data dashboards and reports to external and internal stakeholders, including development of performance programs, in coordination with FDA executive leadership.
- E. Conducts analysis and planning related studies to improve performance, and to support resource requests submitted by FDA components, as well as develops recommendations for the Commissioner, to fulfill FDA, DHHS, and OMB requirements.
- F. Represents the performance planning aspects of the FDA's program integrity and enterprise risk management functions.
- G. Maintains, analyzes, and reports FDA-wide performance information and achievements to external stakeholders.
- H. Develops, implements, coordinates, and oversees the FDA's performance management program, in support of FDA User Fee programs, FDA mission and objectives, and in accordance with the Government Performance and Results Modernization Act, the DHHS strategic plan, and other DHHS organizations.
- I. Partners and collaborates with FDA components to prepare and report the performance goals and results in the FDA's budget; to develop the annual User Fee performance reports to Congress; to identify, analyze, and implement internal and external best practices to improve overall performance, processes, as well as performance objectives and goals.

7. Authority and Effective Date.

The functional statements for the Office of Planning, Evaluation, and Risk Management were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of Planning, Evaluation, and Risk Management**

Office of
Planning, Evaluation, and Risk Management

Administrative Staff
Strategic Planning & Change Management Staff
Evaluation & Analytics Staff
Enterprise Risk Management Staff
Performance Management Staff

(DCAG)

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

Administrative Staff (DCAG1)
Strategic Planning and Change Management Staff (DCAG2)
Evaluation and Analytics Staff (DCAG3)
Enterprise Risk Management Staff (DCAG4)
Performance Management Staff (DCAG5)