

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, and Acquisitions

Office of Acquisitions and Grants Services

Division of Policy, Systems and Program Support

Effective Date: December 14, 2018

1. Division of Policy, Systems and Program Support (DCNEBE).

- A. Formulates the Food and Drug Administration (FDA)-wide acquisition policies governing Office of Acquisitions and Grants Services (OAGS) operational Divisions, provides advice and technical assistance on matters related to FDA acquisition programs, and monitors the adoption of acquisition policies by the Department to ensure consistent policy interpretation.
- B. Responds to contract related Freedom of Information Act (FOIA) requests, and ratifications of unauthorized procurements.
- C. Provides system support and serves as the Purchase Request Information System (PRISM) focal point for developing, coordinating, and implementing enhancements/upgrades or process changes to PRISM/OCI/Unified Financial Management System (UFMS)/Department Contract Information System (DCIS) to assist users in accomplishing the mission of the organization.
- D. Provide technical and acquisition support to OAGS and the FDA Centers to develop robust, actionable contracts in response to acquisition requirements.
- E. Facilitates collaboration between OAGS and all FDA Centers/Offices for development of acquisition requirements via in-person and virtual meetings, working sessions, and training sessions
- F. Provide training, consultation, and templates for structuring and conducting acquisitions including development and refinement of Statements of Work (SOW), Instructions to Offerors, Evaluation Factors, and appropriate proposal submission instructions for industry performers.

- G. Provide technical support in the development of requirements including market research, independent government cost estimate (IGCE) development, SOW, and business proposal cost analysis.
- H. Facilitate proposal reviews with Program Advisory Groups (PAGs) to support consensus determination of technical merit
- I. Oversee workload distribution and contract status for OAGS via the Acquisition Tracking System (ATS). Provide support for ATS end users, including facilitation of enhancements with OIM, coordination of system updates, training of OAGS staff, and regular reporting functions to OAGS.
- J. Perform monthly and quarterly analyses of financial reports and data to monitor fluctuations, trends and unusual variances and provide an accurate view of FDA's acquisition spend. Develop reports and analyses to senior management, FDA Center/Offices, and Chief Financial Officer (CFO) to ensure FDA goals and objectives are being met.
- K. Provide support and serve as the focal point for developing and coordinating the Advanced Acquisition Plan (AAP); communicating any changes of the process to the FDA Center Liaisons; and conduct monthly data analysis for submission to management.
- L. Facilitate the yearly Small Business Outreach in an effort to allow small businesses an opportunity to meet with the Department of Health and Human Services (HHS) Small Business Specialists, FDA Center Program Managers and FDA Contract Officers/Specialists to discuss procurement opportunities and provide an understanding on how to do business with the government.

2. Training and Development Branch (DCNEBE1)

- A. Provides training and development of entry level Contracts Specialists.
- B. Conducts training for Midlevel and Senior level OAGS Contract Specialists and Contracting Officers.
- C. Provides overflow processing of procurement actions, below \$25,000.

3. Acquisition Policy and Oversight Branch (DCNEBE2).

- A. Provides policy guidance and technical assistance to the greater FDA acquisition community.
- B. Develops and implements internal FDA acquisition policies in the form of Policy and Procedure Memoranda (P&PM), Policy Flashes, and Staff Manual Guides (SMGs).
- C. Reviews FDA's highest risk contract actions to ensure compliance with

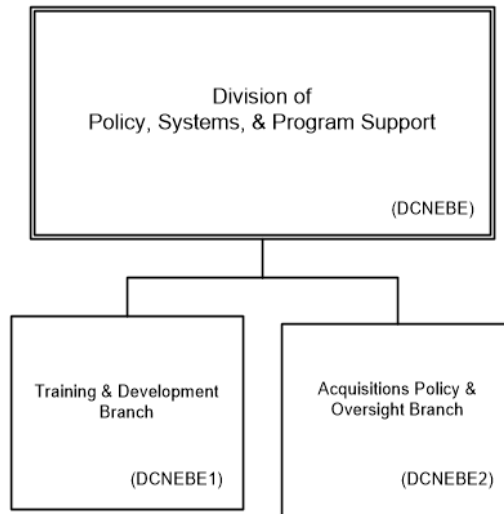
applicable laws, regulations, HHS and FDA-specific policies.

- D. Advises contracting and program staff on acquisition policy and regulatory matters.
- E. Serves as a primary liaison between FDA, HHS [including the Office of General Counsel (OGC)] and other Government agencies in acquisition matters.
- F. Serves as the focal point for protest actions and coordinating protests filed with the FDA, HHS, and the U.S. Government Accountability Office.
- G. Manages the FDA-wide training and certification programs for Contracting Officers (COs), Contracting Officer Representatives (CORs), and Program and Project Officers (P/PMs).

4. Authority and Effective Date.

The functional statements for the Division of Policy, Systems and Program Support were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Operations
Office of Finance, Budget, and Acquisitions
Office of Acquisitions and Grants Services
Division of Policy, Systems, and Program Support**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Finance, Budget, and Acquisitions, Office of Acquisitions and Grants Services, Division of Policy, Systems, and Program Support organization structure depicting all the organizational structures reporting to the Director.

These organizations below report to the Division of Policy, Systems, and Program Support (DCNEBE)

Training and Development Branch (DCNEBE1)

Acquisitions Policy and Oversight Branch (DCNEBE2)