

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF OPERATIONS

OFFICE OF INFORMATION MANAGEMENT AND TECHNOLOGY

OFFICE OF INFORMATION MANAGEMENT

Effective Date: July 22, 2015

1. OFFICE OF INFORMATION MANAGEMENT (DMMHA).

- A. Develops the architecture standards, policies, governance, best practices and technology road map that support the business priorities of the Agency including managing information technology infrastructure, telecommunications, security, strategic planning, capital planning and investment control, enterprise architecture, and applications development and management.
- B. Provides advice and assistance to the Commissioner and senior management officials on Information Technology (IT) resources and programs.
- C. Establishes and oversees implementation of the Agency's IT policy and governance, procedures and processes to bring the agency in conformance with the Clinger/Cohen Act and the Paperwork Reduction Act.
- D. Provides leadership and direction regarding all aspects of the Agency's records management program.
- E. Works in full partnership with the Agency's business areas, develops and communicates the overall vision for the Agency's (IT) program.
- F. Represents the Agency IT programs on internal and external meetings and workgroups on Agency information technology programs and issues (e.g., Health and Human Services (HHS) Chief Information Officer (CIO) Council, Agency Leadership Council, Agency Level Review Boards, etc.).
- G. Establishes policies and procedures for system risk assessments and system business continuity and contingency planning.

- H. Provides consultation to the CIO and other key Agency officials on activities that affect Agency-wide information technology programs, projects, and initiatives. Informs appropriate Agency staff of the decisions and assignments made by the CIO.
- I. Develops and maintains management information necessary for monitoring the CIO's and Agency's information technology goals, priorities, strategies, and activities including recommendations, correspondence control and preparing special reports.

2. INFORMATION SECURITY STAFF (DMMHA1).

- A. Directs and oversees the IT security program.
- B. Ensures and promotes the confidentiality, integrity, and availability of Agency IT networks and information in compliance with individual privacy and civil liberties and with Federal, Department and Agency security requirements.
- C. Oversees Agency IT security policies, standards, and guidelines as necessary to implement the Agency IT Security Program, and monitors their implementation.
- D. Directs, manages, and oversees the intelligence-driven threat mitigation and capability that enables the integration of intelligence, counterintelligence, insider threat, and operational/cyber security principles.
- E. Establishes and maintains liaison relationships with federal partners on IT and cyber security matters.
- F. Maintains the Homeland Secure Data Network (HSDN) to support IT security and cyber operations.

3. KNOWLEDGE MANAGEMENT STAFF (DMMHA2).

- A. Provides research support to Agency through delivery of information consulting and advisory services, literature searches, and document delivery services in order for Agency to carry out its public health mission.
- B. Collaborates with Agency researchers on research projects, bibliographies, internal publication databases, copyright issues, digitization and more, so Agency has the information it needs to meet its scientific and regulatory mission.

- C. Plans, develops and conducts training sessions so customers can access and utilize online resources available to them to enhance their research efforts.
- D. Provides stewardship for a unique, valuable, and specialized collection of materials essential to Agency's scientific, legal, administrative and regulatory staff.
- E. Collects, organizes, maintains and preserves information resources, in multiple formats, in all areas of Agency's research and regulated products, including: biologics, blood products, cosmetics, devices, drugs, food processing and safety, nutrition, pharmacy, pharmacology, radiology, tobacco, toxicology, and veterinary medicine.
- F. Increases awareness of library services, staff expertise, and its research by promoting the library to customers. Provides services and resources to Agency, Health and Human Services (HHS), other Federal employees and the public on a limited basis.
- G. Selects, evaluates, acquires and/or develops, and provides electronic access to scientific and technical databases, publications and other media mechanisms in support of Agency-wide research needs.
- H. Partners with libraries and information Centers, publishers, consortia across the Federal Government, health related associations, and other organizations to enhance resource sharing opportunities that provide cost savings, sharing of skills and knowledge, benchmarking best practices, and fostering collaborations that have a beneficial impact on the library and Agency's work.

4. ENTERPRISE ARCHITECTURE AND TECHNOLOGY INNOVATION STAFF (DMMHA3).

- A. Strengthen partnerships with all Agency components, OPDIVs, Departments, Academia, Industry, International collaborators, Law enforcement and Media.
- B. Provides advice, expertise, and direction in the areas of market research, enterprise architecture, security and privacy, infrastructure including hybrid cloud, mobility, and collaboration. Liaise with the IT PMO and Office of Acquisitions and Grants Services (OAGS) to ensure capital planning and acquisition guidelines are appropriately met for agile development.
- C. Explores healthcare IT solutions (e.g. electronic medical records, data standards, etc.) for Agency's space in collaboration with ONC, CMS and other OPDIVs.

- D. Ensures alignment with Agency and Center-specific priorities for agile innovation and technology.
- E. Conducts studies and analyses and performs capacity planning to determine appropriate IT hardware, software and infrastructure requirements. Ensures Agency infrastructure is kept up to date with Agency technology standards.
- F. Provides technical consultation to OIM organization structures in identifying appropriate IT hardware, software and infrastructure requirements for new IT applications that support Agency business process needs.
- G. Ensure adherence of Agency systems activities to enterprise architecture policies, standards and procedures.
- H. Establishes and implements an Enterprise IT Common Component Framework containing modules/services to be shared across the Agency's information systems and maintains Agency's enterprise applications.
- I. Assists in development and maintenance of Agency's policies and procedures for independent verification and validation of IT systems.
- J. Develops implements and provides problem management processes for the Agency systems, including trend analysis of problems. Develops standard IT reports.
- K. Coordinates the development and implementation of Agency Data Administration policies, standards and procedures to ensure design consistency, including review of work products for compliance with standards and enterprise architecture.
- L. Evaluate Agency's new enterprise requirements and solutions, or new enhancements where applicable adherence with OMB sanctioned plans such as cloud computing and incremental deliveries.
- M. Validates specifications, requirements, procedures guidelines and design of new enterprise requirements and solutions, new enhancements where applicable, or system upgrades or changes are in compliance with enterprise architecture. Performs enterprise systems analyses, develops and implements testing plans.
- N. Assists in the development and implementation of technical specifications and plans for procurement of cloud services, scientific and high

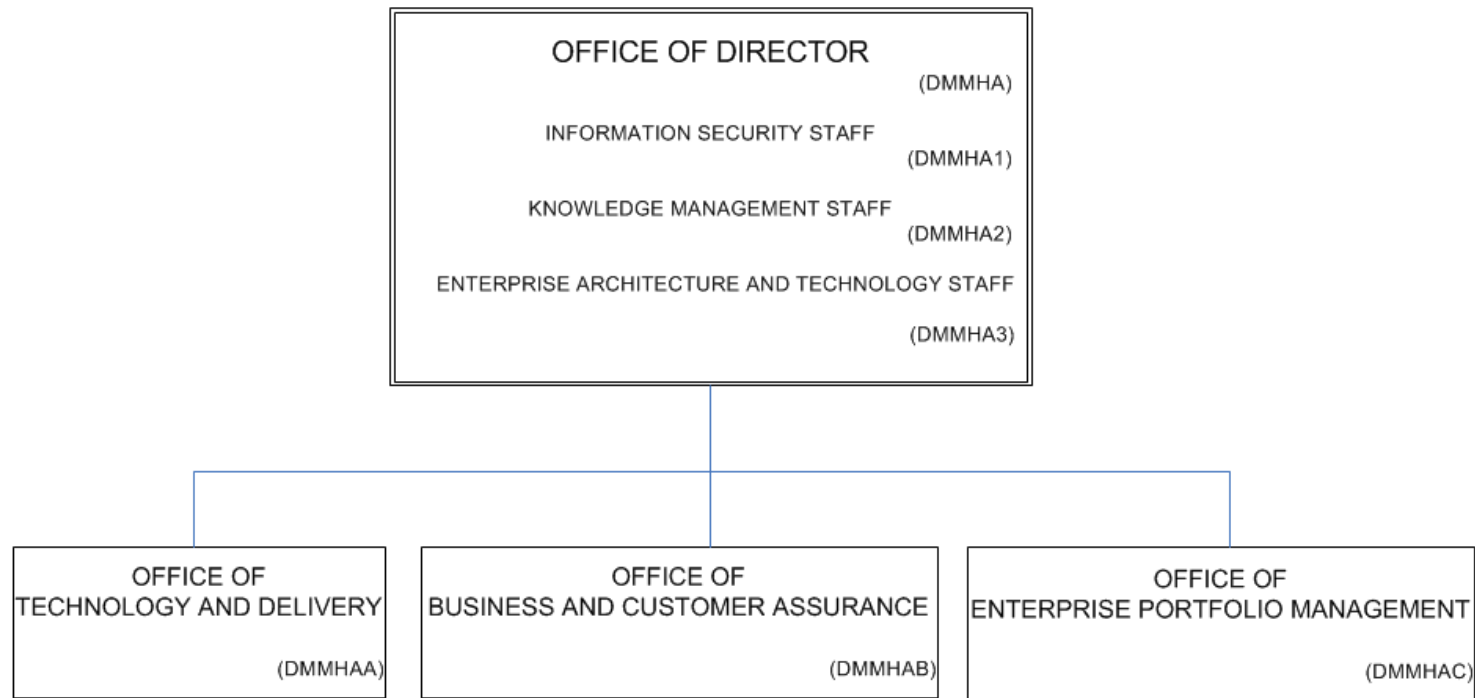
performance computing, and IT equipment (hardware and software) and support resources required for the integrating of new system designs.

- O. Leads Agency's strategy, development, and implementation of 1) cloud, high performance and scientific computing, b) sharing publically safe information and applications with the general public, and c) new innovations.

5. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Acting Commissioner for Food and Drugs, and effective on July 22, 2015.

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The following is the Food and Drug Administration, Office of Operations, Office of Information Management and Technology, Office of Information Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DMMHA):

- Information Security Staff (DMMHA1)
- Knowledge Management Staff (DMMHA2)
- Enterprise Architecture and Technology Innovation Staff (DMMHA3)
- OFFICE OF TECHNOLOGY AND DELIVERY (DMMHAA)
- OFFICE OF BUSINESS AND CUSTOMER ASSURANCE (DMMHAB)
- OFFICE OF ENTERPRISE PORTFOLIO MANAGEMENT (DMMHAC)