

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office Enterprise Management Services

Division of Information Governance

Effective Date: December 14, 2018

1. Division of Information Governance (DCNAC).

- A. Establishes Food and Drug Administration (FDA) policy and standards for Office of the Commissioner Records Management activities by providing standardized procedures and processes for continuity and organizational efficiencies.
- B. Provides oversight, guidance and approval of FDA Programmatic, Administrative and Center Records Control Schedules.
- C. Conducts business analysis, inventories and remediation/clean-up activities by supporting Assistant Records Liaison Officers (ARLO).
- D. Formulates and executes Federal Records Center physical records storage and retrieval budget. Inspects and approves record storage facilities according to NARA guidelines.
- E. Develops web-based and in-person annual and new employee training.
- F. Coordinates communications with Health and Human Services (HHS) and Office of Management and Budget (OMB) on all Paper Reduction Act information collection related activities and ensures FDA does not overburden the public with federally sponsored information collections.
- G. Coordinates projects and timeline milestones with FDA centers. Review content in notices and coordinate with Regulations Policy Management staff, notice's publication in the Federal Register.
- H. Oversees entry and transmission of information collection requests through HHS to OMB. Ensure that existing approvals by OMB are renewed on time without expiration of approval.
- I. Reviews justification statements provided by centers.

- J. Ensures procedures pursuant to the Paperwork Reduction Act of 1995 are followed across FDA.
- K. Acts as the liaison between FDA centers, HHS and OMB on all information collection matters.
- L. Assists internal and external requesting entities in the initiation of requests for electronically stored information (ESI) through the development of an appropriately narrow search scope and defined search terms.
- M. Searches information technology (IT) infrastructure to collect responsive ESI in response to investigative, legal and legislative requests.
- N. Facilitates litigation holds and assists in the dissemination of hold notifications to Center ARLO's to aid in the preservation of identified records.
- O. Assists in the development of legal search and collection tools.
- P. Coordinates, develops IT-based training for legal.
- Q. Ensures FDA-wide compliance with the Privacy Act of 1974, privacy provisions of the E-Government Act of 2002 (includes the Federal Information Security Management Act (FISMA)), Executive Orders, HHS and FDA privacy regulations, relevant memoranda issued by the Office of Management and Budget (OMB), HHS and FDA policies, and any other relevant law or guidance.
- R. Works with FDA components and programs to ensure that privacy concerns and compliance requirements are addressed in the design, implementation, operation, and other phases of each system, program, or initiative.
- S. Ensures compliance with privacy laws, regulations, and authorities.
- T. Responds to privacy incidents and breaches as well as complaints involving unauthorized access, use, disclosure, or other compromising of PII.
- U. Provides training, education, and outreach to build and maintain a culture of privacy within FDA and promote transparency to the public.
- V. Processes all Privacy Act requests received by the FDA.
- W. Evaluates FDA regulatory proposals and contractual agreements involving collection, use, and disclosure of PII.
- X. Ensures Fair Information Practice Principles of notice and transparency are incorporated into the FDA's collection, maintenance, and sharing of personally identifiable information (PII).

- Y. Conducts [Privacy Impact Assessments](#) (PIAs) for all information systems and collections, and other publications.

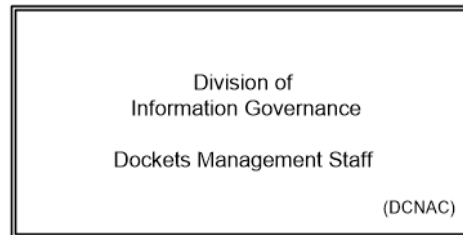
2. Dockets Management Staff (DCNAC1).

- A. Receives, examines and processes submissions required or permitted in FDA administrative proceedings; establishes and maintains docket files containing FDA official records relating to an administrative proceeding. Disseminates submissions to appropriate offices for action. Routinely coordinates activities of the branch with other appropriate components.
- B. Serves as the FDA expert on requirements for submissions required or permitted in FDA administrative proceedings. Participates in the development of regulations and policy impacting on FDA administrative proceedings.
- C. Provides staff support for FDA rulemaking activities. Determines compliance of petitions, comments, request for hearings, motions, briefs, and objections with FDA regulations.
- D. Provides information access via the Intranet and other means to FDA personnel for Dockets Management materials and to copyrighted documents.
- E. Plans and conducts FDA-wide analytical reviews and studies to assess and manage information and access concerns. Makes recommendations and assists in the implementation of the recommendations.

3. Authority and Effective Date.

The functional statements for the Division of Information Governance 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 the Enterprise Management Services
Division of Information Governance**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Enterprise Management Services, Division of Information Governance organization structure depicting all the organizational structures reporting to the Director.

These organizations below report to the Division of Information Governance (DCNAC)
Dockets Management Staff