## FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

### **INFORMATION RESOURCES MANAGEMENT - RECORDS MANAGEMENT**

## **ESSENTIAL - VITAL RECORDS MANAGEMENT POLICY**

Effective Date: August 7, 2018

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#### 1. PURPOSE.

The purpose of this Staff Manual Guide is to promulgate procedure, policy and guidance for support of the Food and Drug Administration (FDA) Essential and Vital Records Program.

#### 2. POLICY.

All federal records designated as vital or essential to the operation of the FDA and which, if destroyed, would seriously impair or disrupt FDA mission critical functions must be identified, documented, protected and tested in accordance with Federal Directives and Guidelines.

#### 3. LIMITATIONS.

A. This Guide does not address the protection of automated information systems. Staff Manual Guide 3252.11, *Information Resources Management - Information Technology Security Operational Controls Policies, Information System* 

SMG 3291.9 (08/07/2018)

*Contingency Planning*, outlines the requirements for assuring availability of systems in the event of a disruption.

- B. This Guide does not address the protection of classified information relating to the national security and defense of the United States; that information is contained in the Department of Health and Human Services (DHHS) Security Manual, or the handling of Controlled Unclassified Information; that information is contained in 36 Code of Federal Regulations (CFR) 2002 - Code of Federal Regulations Part 2002 Controlled Unclassified Information (CUI).
- C. This Staff Manual Guide is provided as a reference and support guide for Food and Drug Administration staff. This guide has a dependency on Federal Regulations and Guidelines; to include National Archives and Records Administration (NARA), Department of Homeland Security (DHS), Federal Emergency Management Agency (FEMA) and FDA Continuity of Operations Planning (COOP).

# 4. AUTHORITIES.

- A. 36 CFR 1223, Managing Vital Records
- B. 44 U.S.C. 3101, Records management by agency heads; general duties
- C. Executive Order 12656, National Defense Resources Preparedness
- D. Executive Order 13231, Critical Infrastructure Protection in the Information Age
- E. Executive Order 10346, Preparation by Federal Agencies of Civil Defense Emergency Plans
- F. National Security Presidential Directive 51
- G. Homeland Security Presidential Directive 20
- H. Federal Continuity Directive 1, Federal Executive Branch National Continuity Program and Requirements,
- I. Federal Continuity Directive 2, Federal Executive Branch Mission Essential Function and Primary Mission Essential Function Identification and Submission Process.
- J. For Background Details see Appendix B.

# 5. RESPONSIBILITIES.

- A. **FDA Commissioner and the Deputy Commissioner for Operations**: The FDA Commissioner is ultimately responsible for creating and preserving records, including essential and vital records that adequately and properly document the organization, functions, policies, decisions, procedures, and essential transactions of FDA. The responsibility for establishing a program to ensure compliance with applicable Federal laws and regulations has been delegated to the Deputy Commissioner for Operations, Office of Information Management and Technology (OIMT).
- B. **FDA Chief Information Officer (CIO)**: The Chief Information Officer in OIMT is responsible for providing the leadership, planning, overall policy, guidance, and general oversight of records management in FDA, and its incorporation into the broader information resources management framework. The CIO will:
  - 1. Incorporate records management requirements and policies, including those related to essential and vital records, into the Agency's overall information resources management (IRM) policy and planning.
    - a. Designate in writing an FDA (Agency) Records Officer responsible for, among various aspects of that program, providing support to a vital records program.

## C. Center/Office Directors:

- 1. Designate in writing an Assistant Records Liaison Officer (ARLO) accountable to the FDA Records Officer who is designated to oversee the program.
- 2. Ensure the ARLO has adequate skills, training, resources, time, and appropriate authority to do the job.
- 3. Implement a records management program within their area of responsibility to accomplish the objectives identified in Federal regulations and HHS/FDA policies and procedures. Minimum program components include responsibilities for:
  - a. Providing support to a vital records program. While emergency operation records should be identified and managed in the Continuity of Operations Plan (COOP), ARLOs need to work with the FDA COOP coordinators to ensure all records are identified and protected. The location and access rights for the legal and financial rights records are to be included in the COOP.
- 4. Identification of Essential Mission Functions

- D. Business/Records Owners: Business/Records Owners are responsible for identifying and ensuring the protection of essential/vital records as described in this document.
- E. **Center/Office Information Technology Organizations**: Center/Office Information Technology Organizations are responsible for oversight of essential/vital records in their respective area. In addition, this group must incorporate these guidelines into the broader information resources management IT framework. The Organization's Leadership must:
  - Incorporate records management requirements and policies, including those related to essential/vital records, into the Center/Office's overall information resources management (IRM) policy and planning and will ensure that processes are in place to support IT requirements as they relate to supporting essential/vital records in the case of an emergency/ interruption from normalcy of any type.
- F. **Senior Field Management Officials**: Senior Field Management Officials have overall responsibility for the protection and accountability of essential and vital records to protect and ensure the records that are the most vital to the FDA. While they may delegate this responsibility, they retain ultimate responsibility.
- G. FDA personnel, including, but not limited to civilian government employees, contractors, political appointees, local or foreign government exchange program participants, Commissioned Corps personnel, guest researchers, visiting scientists, fellows and interns, are responsible for supporting the essential and vital records policy.

# 6. ESSENTIAL AND VITAL RECORDS PROTECTION METHODOLOGIES

A. FDA Essential and Vital Records must be identified and protected from potential loss. The protection method required is based on record media type, available resources, and environmental and security requirements – and on an assessment of the risks for each method. Federal Continuity of Operations mandates and directives require the traceability of essential and vital records back to the essential functions that they support. There are two common methods of protecting Essential and Vital Records: dispersal and protective storage. Dispersal is the distribution of duplicate copies of records or information to locations other than those where the originals are housed; this may be part of a routine business process or specifically designed to protect identified Essential and Vital Records. Regardless of the methods selected, procedures must be implemented to ensure the Essential and Vital Records are kept current for the Essential and Vital Records program to be effective.

- 1. Essential and Vital Records shall be (1) secured in a manner that preserves and protects the integrity of the records and (2) protected via dispersal or protective storage, or a combination of both.
- 2. Acceptable means of protecting Essential and Vital Records via dispersal and protective storage, include but are not limited to, the following examples:
  - a. Storing physical Essential and Vital Records in a file cabinet in the office with the copy stored in a locking fire-resistant cabinet in a different building on the campus (example of combination of dispersal and protective storage)
  - b. Storing physical Essential and Vital Records in a locked on-site facility with the copy stored at an offsite facility designed for records protection (example of combination of dispersal and protective storage)
  - c. Storing physical Essential and Vital Records in a locked, fire-resistant vault located in an off-site facility designed for records protection (example of protective storage);
  - d. Storing electronic Essential and Vital Records on a networked shared drive or other system with a backup of that record being stored and managed by the appropriate data center; with the backup tape or disc being stored or replicated off-site (example of combination of dispersal and protective storage).
- 3. The manner in which Essential and Vital Records are protected (i.e., via dispersal alone, via protective storage alone, or via a combination of both) is determined by the level of risk associated with the potential loss of that Essential or Vital Record. Generally, the greater the risk associated with loss and the greater the level of difficulty and cost to reconstruct, the greater the protection. Records considered to be at highest risk should be protected by both dispersal and protective storage. Further, regarding dispersal of records, the greater the risk, the greater the geographic separation of the duplicates of those records to make it less likely that a disaster in the immediate area would impact the location where the duplicate records are stored. The degree and type of protection shall be determined by the record owner and Center/Office Assistant Records Liaison Officer working with the Agency Records Officer, appropriate information technology staff, and, if necessary, Senior Management.
- B. The determination of the status of Essential and Vital Records shall be made based on the subject content of the record or information and shall not be tied to media format.

- C. Records and information shall be identified as Essential and/or Vital Records only for as long as they support critical/essential business functions and processes they are required for.
- D. A Recovery Class Priority Level must be assigned to the Essential and/or Vital Record to denote recovery timeframe requirements. Recovery Priority Levels define the timeframe for recovery of Essential and/or Records; they do not define or impact the level or type of protection assigned to the Record nor do they denote the level of criticality and importance of a given Essential and/or Vital Record.

Level	Definition
Recovery Priority Level 1	Records or information needed for emergency operations (one example of this type of record is the Vital Records
	Listing/Log for the Center/Office).
Recovery Priority Level 2	Records or information needed within the first 24 hours after a disaster for immediate resumption and continuation of business.
Recovery Priority Level 3	These records and information are essential for reestablishing the legal and regulatory position of the agency and are needed within the first 72 hours after a disaster.
Recovery Priority Level 4	These records are vital but do not require recovery within the first 72 hours after a disaster.

# Priority Levels – Diagram A-1

Only a certain subset of your Center's or Office's records may be found to be vital or essential, meaning they will be critical in an emergency. It is difficult to decide which records are essential or vital, and some instructions for doing so are presented in this guidance. In making this determination, the most crucial question is: Are these records vital to continuing the Food and Drug Administration's mission critical functions?

While much of the work that we do supports these efforts, some records are critical for continuation of functions and cannot be lost even in the most drastic situation. These records must be safeguarded/duplicated and stored off-site and in a location that will allow ease of access.

Essential Records are defined as, "Information systems and applications, electronic and hardcopy documents, references, and records needed to support essential functions during a continuity event." The two basic categories of essential records are emergency operating records and rights and interest records. Emergency operating records are essential to the continued functioning or reconstitution of an organization. Rights and interest records are critical to carrying out an organization's essential legal and financial functions and vital to the protection of the legal and financial rights of individuals who are directly affected by that organization's activities; vital records are a subset of essential records. <u>Federal Continuity Directive 1 (FCD 1) 2017</u>.

## 7. ESSENTIAL AND VITAL RECORDS IDENTIFICATION AND PROTECTION

The ability to identify, and further, the ability to access the critical information a Center or Office needs to perform its key functions in the case of an emergency is crucial in the process of contingency planning so the Center or Office is ready in the case of a disaster.

36 CFR 1223.16 requires, in part that Agencies identify essential and vital records in the context of the emergency management function. The informational content of records series and electronic records systems determines which are essential and vital records. Only the most recent and complete sources of the information are essential and vital records.

Contingency planning is a significant component of the Agency's Essential and Vital Records Program which works with the Centers and Offices to enable them to identify and protect essential and vital records. This program works in coordination with COOP to support contingency planning FDA wide.

Essential functions are those functions that enable Federal Executive Branch agencies to provide vital services, exercise civil authority, maintain the safety and wellbeing of the general populace, and sustain the industrial/economic base during an emergency. By identifying these functions, Centers and Offices can identify the records and information associated with their operations. The Operational Concept or similar section in each Center or Offices, or any Staff Division, COOP Plan should include the identification of those functions deemed essential.

Below is a seven step process each Center or Office should use to identify and protect its essential/vital records

Step 1 – Current State Analysis.

Using the Essential/Vital Records Schedule template/instructions in Appendix A, ensure your Center/Office state is current for your specific entries to determine your baseline. Note: A new start is considered an initial baseline. If you have an existing baseline, your baseline needs to be updated at least every six months.

Step 2 – Document your Center/Office essential records.

Review the information and records maintained in/by your office and determine which ones would be needed in an emergency. The easiest way to do this is to determine your office's essential functions. **NOTE**: Essential Function documentation for your office may already exist. Document the records that support each essential function. Compare your listings to FDA's Mission Critical Functions provided to leverage your critical records. Use the Essential/Vital Records Schedule template found in Appendix A to update your baseline if you currently have vital records data in another format.

If no such identification process has taken place, work with your Center's or Office's COOP Coordinator and other appropriate COOP Team Members to identify and document the essential functions.

There are four Priority Tiers/Recovery Classes of vital records protection that the FDA uses as documented in the diagram above (Priority Levels – Diagram A-1)

Provided below, you will find a Tier breakout which includes examples. These generally mirror the Recovery Class Priority Level in the section above:

Tier One: Those records necessary in the first few hours of a crisis.

Records that may be needed immediately

- a. Emergency preparedness plan (such as the Occupant Emergency Plan and the Continuity of Operations (COOP) Plan)
- b. Emergency telephone tree
- c. Delegations of authority
- d. Security clearance roster
- e. Office evacuation blueprints and maps (so emergency workers will know where they are going)
- f. Policy for talking to the media
- g. Copy of vital records inventory

Many of these records will be included in the center/office/division associated COOP plan. For this reason, they are also known as "COOP vital records."

Tier Two: Those records necessary to respond to an emergency. These records involve only the work which is necessary to handle the crisis; it is assumed that no day-to-day work will be done until the building is reopened, and/or there is virtual access to the records.

Records that may be needed to respond to the crisis

- a. System manuals for critical electronic databases and local area networks (LANs)
- b. Regulatory information (e.g., copies of regulations or data on air quality, etc., so important environmental monitoring work can continue)

Records that may be needed to provide employee benefits

- a. Personnel records for all employees, including medical records
- b. Time and attendance records (e.g., those located in IO/Program)

Records that may be needed to get back into the office

- a. Combinations and/or keys to get into locked areas
- b. Records recovery information (e.g., phone numbers of salvage companies)

Tier Three - Those records involving specific activities which are the most critical to the FDA mission.

This tier assumes that the normal FDA records are unavailable for a prolonged period due to an emergency which causes long-term displacement of personnel and equipment from the work site to a new operating location. Most of the day-to-day work in this catastrophic situation would need to be recreated.

This includes any program-specific records on activities deemed to be of critical importance, meaning the work cannot be interrupted, even if—as in the worst case —the building has been destroyed and all the FDA records are lost. The determination of tier three records must be made by each office. If an office decides that none of their work rises to this level of importance, there will be no Tier Three or Tier Four records.

There is a link between vital records and COOP. Therefore, one of the criteria that can be used to determine an office's Tier 3 vital records is what the office has defined in its COOP Plan as "essential functions." Any records deemed necessary in supporting the office's essential functions should be a part of the office's set of vital records.

Tier Four - records are essential but do not require recovery within the first 72 hours after a disaster.

The acid test for vital records is as follows: for each record thought to be vital, ask:

- a. Can office's Agency critical work continue without record?
- b. Can a specific record be found elsewhere or reconstructed?

- c. Is the record already protected elsewhere?
- d. Is the record considered unique and irreplaceable?

Step 3 – Prepare Essential Records/Vital Records Inventory

Prepare an inventory of the records identified in Step 1. Decide who needs to have copies and establish a procedure to ensure the inventory is updated and sent to the appropriate people.

Everyone's cooperation is needed when preparing the inventory. It is necessary for the following people to be involved:

- 1. Agency Records Liaison Officers (ARLOs) serve as vital records specialist and aid in implementing the vital records program for their specific area.
- 2. COOP Representatives also serve as vital records specialist and aid the ARLOs and Vital Records Coordinators in implementing the vital records program for their specific area.
- Management support Vital Record Collection goals and initiatives. This
  includes revising priorities of the staff to allow time to support the vital records
  policy.
- 4. Database Managers and LAN Administrators Ensure electronic systems in their control are regularly backed up and accessible in an emergency. This may require storing copies and equipment to read the copies offsite.
- 5. Records Coordinators Support their organization's efforts to manage records. Provides communications to and from the Center or Office ARLO relating to the records management program, and provide information and assistance to staff relating to records management issues.
- 6. FDA Personnel Provide support and assist where needed.

Step 4 – Determine how the records will be protected.

Now that you know which records in your office are vital and where they are located, you need to determine how to protect them. There are two basic choices: (1) duplicate them and store them offsite; or (2) collect them from other sources and recreate them so they will be available virtually if needed.

The following is a list of questions that will assist you in making your decision.

1. Can these records be found in locations other than this office and geographic location?

- 2. Is the information contained in these records available in an electronic system or database?
- 3. What is the most cost effective manner to recreate these vital records (e.g., storage on compact discs, photocopying, collecting them from another source)?
- 4. Do these records contain any sensitive information (e.g., SSN) which would require special handling?
- 5. How often does the information need to be updated and who will be responsible for updating it?

**NOTE**: If you will be duplicating information, use electronic media whenever possible since the cost to reproduce and store information electronically will be less than duplicating and storing paper. It is also critical to have a backup in case the primary electronic system fails. This can be accomplished by copying onto IRONKEYS or other secure protected devices.

However, electronic media does have some potential pitfalls. Here are some issues to consider:

- a. Migrate information to new media when software and hardware changes. Records which cannot be read with existing equipment are useless.
- b. Test the information once it is copied to be sure there are no errors. If there was an error when it was copied, waiting until you're trying to recover from a disaster is the wrong time to find out.

Step 5 – Designate an offsite storage location.

Based on the decisions made in Step 3, it is likely you will need to find an offsite location to store duplicates. Here are some things to consider when selecting a location:

- 1. Fifty miles is considered sufficiently close for access, but far enough away so that the records will not be vulnerable for most emergencies. However, considering worst-case local emergencies, offsite storage outside this radius should be considered.
- 2. Records which will be needed immediately, such as the emergency preparedness plan and telephone tree, can be stored in a manager's home. However, it is important that another copy be stored in the central location for off-site storage. That will allow access to the record if the manager is not available.

- 3. Other FDA COOP relocation offices (Other FDA Region Offices), as well as the local Federal Records Center or approved commercial offsite storage, may be choices to consider.
- 4. You may need equipment (e.g., laptops/computers, microfilm readers) to read the records.
- 5. The records will need to be easily accessible based on Tier; therefore, they should be stored as close to the facility for emergency off-site operations as possible. In some cases, approved commercial storage allows immediate access to the records at all times, which may not be possible at a government facility. However, you would have to assure that all methods of storage are approved by senior management.

Step 6 – Protect the records.

Finally, once you have decided how the records are to be protected, add the information to your inventory. The inventory should show:

- 1. The method of protection (e.g., photocopies);
- 2. How often the records are updated (the rotation schedule) and who does it; and,
- 3. Contact information if the records are to be collected from other locations.

Records should be updated as often as possible. Consider the risk to the recovery effort if the information is out of date. Consider the cost of keeping it updated.

Ensure that any other documents which contain information related to the office's vital records program, such as the office's COOP, reflect the most updated vital records program-related information.

Create a resource list of disaster recovery firms for your geographic area and update the information at least annually.

Don't forget to test your plan to be sure the recovery runs smoothly. Include drills on using the equipment, supplies, and procedures for vital records recovery.

Step 7 – Senior Management sign off.

The Vital Records Schedule is a working document. Once you have completed incremental updates, ensure that you get Senior Management signoff.

# 8. TRAINING AND AWARENESS.

SMG 3291.9 (08/07/2018)

Essential and vital records training and awareness programs should be made available for appropriate staff across the Agency.

## 9. REVIEW AND AUDITS.

Essential and vital records audits, reviews and testing will be required at minimum yearly and should be coordinated with COOP testing.

# **10. EFFECTIVE DATE.**

The effective date of this guide is August 7, 2018.

# 11. Document History – SMG 3291.9, "Essential – Vital Records Management Policy"

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/06/2018	N/a	OO/OIMT/OIM/ OBCA/RERM	FDA Chief Information Officer

# **APPENDIX A - Vital and Essential Records Inventory Form**

## **APPENDIX B**

#### Background

The Federal Records Act of 1950, as amended, requires all Federal agencies to make and preserve records containing adequate and proper documentation of the organization, function, policies, decisions, procedures, and essential transactions. These records are property of the federal government and must be managed according to applicable laws and regulations.

The Federal Records Act also requires agencies to establish a records management program. This program is defined as a planned, coordinated set of policies, procedures, and activities needed to manage its recorded information. Among the regulations associated with this Act, 36 CFR 1223, Managing Vital Records, requires agencies to establish a program to identify, protect, and manage vital records as part of an agency's continuity of operation plan designed to meet emergency management responsibilities. Such a program must provide an agency with the information it needs to conduct its business under other than normal operating conditions and to resume normal business afterward; and enable agency officials to identify and protect the most important records dealing with the legal and financial rights of the agency and of persons directly affected by the agency's actions.

Executive Orders 12656, Assignment of Emergency Preparedness Responsibilities, and 13231, Critical Infrastructure Protection in the Information Age; and National Security Presidential Directive (NSPD 51)/Homeland Security Presidential Directive (HSPD-20) or applicable successor directives require the head of each agency to make and preserve records that contain adequate and proper documentation of the organization and to perform national security emergency preparedness functions.

36 CFR 1223 also complies with the requirements of Federal Continuity Directive 1, Federal Executive Branch National Continuity Program and Requirements, and Federal Continuity Directive 2, Federal Executive Branch Mission Essential Function and Primary Mission Essential Function Identification and Submission Process.

Executive Order 10346, Preparation by Federal Agencies of Civil Defense Emergency Plans, requires that each Federal agency shall, in consultation with the Federal Civil Defense Administration, prepare plans for providing its personnel, materials, facilities, and services pursuant to the provisions of section 302 of the Federal Civil Defense Act during the existence of a civil-defense emergency. The plans of each agency shall take into consideration the essential military requirements of the Department of Defense with respect to such agency. In each Federal agency shall prepare plans for maintaining the continuity of its essential functions during the existence of a civil-defense emergency.

#### **GLOSSARY/DEFINITIONS**

**Disposal** – The action taken regarding temporary records after their retention periods expire and consisting usually of destruction or occasionally of donation. Also, when specified, "disposal" refers to the actions taken regarding non-record materials when no longer needed, especially their destruction. (See NARA, "A Federal Records Management Glossary.")

**Disposition** – The action taken regarding records no longer needed for current Government business. The actions include transfer to agency storage facilities or Federal records center; transfer from one Federal agency to another; transfer of permanent records to the National Archives; and disposal of temporary records. "Disposition" is also the action taken regarding non-records materials when no longer needed, including screening and destruction.

**Electronic Records** – Any information that is recorded in a form that only a computer can process and that satisfies the definition of a Federal record in 44 U.S.C. 3301. Electronic records include numeric, graphic and text information, which may be recorded on any medium capable of being read by a computer and which satisfies the definition of a record.

This includes, but is not limited to, magnetic media, such as tapes and disks, and optical disks. Unless otherwise noted, recordkeeping requirements apply to all electronic records systems, whether on microcomputers, minicomputers, or mainframe computers, regardless of storage media, in network or stand-alone configurations. (FIRMR Bulletin B-1).

**Essential Records** - Information systems and applications, electronic and hardcopy documents, references, and records needed to support essential functions during a continuity event. The two basic categories of essential records are emergency operating records and rights and interest records. Emergency operating records are essential to the continued functioning or reconstitution of an organization. Rights and interest records are critical to carrying out an organization's essential legal and financial functions and vital to the protection of the legal and financial rights of individuals who are directly affected by that organization's activities. To sum it up Essential Records are the records required to support an organization mission critical and essential functions. Federal Continuity Directive (FCD) 1 2017

**Information System** – Is defined by the Office of Management and Budget (OMB) in Circular No. A-130 as "a discrete set of information resources organized for the collection, processing, transmission and dissemination of information in accordance with defined procedures, whether automated or manual."

**Non-record Materials** – are those Federally-owned informational materials that do not meet the statutory definition of records (44 U.S.C. 3301), or that have been excluded from coverage by the definition. Excluded materials are extra copies of

documents kept only for reference, stocks of publications and processed documents, and library or museum materials intended solely for reference or exhibit. (36 CFR 1220.14)

**Records** – includes all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business, and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decision, procedures, operations or other activities of the Government, or because of the information value of the data in them. (44 U.S.C. 3301).

**Records (Control) Schedule** – A document providing mandatory instructions for what to do with records (and non-record materials) no longer needed for current Government business, with provision of authority for the final disposition of recurring or nonrecurring records. Includes the SF 115, agency records schedules for Agency specific program records and the General Records Schedules (GRS) for common administrative records. Also called records disposition schedule, records retention schedule, or schedule.

**Records Disposition** – is any activity with respect to:

- disposal of temporary records no longer needed for the conduct of business by destruction or donation to an eligible person or organization outside of Federal custody;
- 2. transfer of records to Federal agency storage facilities or records centers;
- 3. transfer to the national Archives of the United States of records determined to have sufficient historical or other value to warrant continued preservation; or
- 4. transfer of records from one Federal agency to any other Federal agency. (44 U.S.C. 2901(5).

**Records Management** – the planning, controlling, directing, organizing, training, promoting, and other managerial activities involved with respect to records creation, records maintenance and use, and records disposition in order to achieve adequate and proper documentation of the policies and transactions of the Federal Government and effective and economical management of agency operations. (44 U.S.C. 2901(2).

**Records Series** – file units or documents arranged according to a filing system or kept together because they relate to a particular subject or function, result from the same activity, document a specific kind of transaction, take a particular physical

form, or have some other relationship arising out of their creation, receipt, or use, such as restrictions on access and use.

**Reference Materials** – Non-record materials. Includes extra copies of documents kept only for convenience of reference, stocks of publications and of processed documents.

**Scheduling** – the process of developing schedules for the disposition of records, along with disposition instructions for non-record materials.

**Sensitive Data** – Sensitive data are data that require protection due to the risk and magnitude of loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. The term includes data whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary data, records about individuals requiring protection under the Privacy Act, and data not releasable under the Freedom of Information Act.

**Staff Division** – Sub-components of the Office of the Commissioner or Center/Office Director

**Vital Records** – Vital Records refers to a specific subset of essential records which are records that are needed to protect the legal and financial rights of the Government and those affected by Government activities (legal and financial rights records). FCD 1 2017,36 CFR 1223.2 (b)