POLICY AND PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

CDER Records Management

Table of Contents

PURPOSE

This MAPP documents the policies and procedures for CDER's Records Management (RM) Program, provides decision-making guidance, defines roles and responsibilities, and assigns accountability for the ongoing governance, daily operations, and processes of the CDER RM Program.

This MAPP also establishes and maintains an understanding of CDER RM requirements, identifies the skills and capabilities required to maintain the CDER RM Program, and identifies where CDER's offices need to incorporate RM controls.

BACKGROUND

Information is a critical asset as CDER regulates prescription and over-the-counter drugs. CDER creates and receives many types of information and documentation requiring storage and management as records. Proper management of these records is vital to the

success of CDER's mission to protect and promote public health. To use appropriate RM procedures, it is necessary to understand that records have a life cycle. As information is received and created by CDER, records need to be identified, maintained, and transferred or deleted according to the appropriate life cycle phase.

CDER must adhere to multiple RM controls, policies, directives, and regulations. CDER is also required to conduct electronic recordkeeping, ensure transparency and accountability, and to demonstrate compliance with federal RM statutes and regulations. The 2011 Presidential Memorandum on Managing Government Records established the beginning of an Executive Branch-wide effort to reform records management policies and practices and establish a framework for the management of government records. The 2016 OMB Circular A-130: Managing Information as a Strategic Resource also specifically references RM requirements.

In FY14, the CDER Office of Business Informatics (OBI) conducted an initial assessment which revealed some CDER RM practices did not meet current federal RM requirements, or the needs of CDER employees. CDER's Executive Committee was briefed on the results, and requested further action be taken. The CDER RM Council (RMC) was soon chartered in an advisory capacity. The CDER RM Program was developed to support the CDER Assistant Records Liaison Officer (ARLO) to improve RM activities in CDER. In 2017, the CDER RM Program Team and RMC recommended that the Records Coordinator (RC) role be established in each office to further improve RM efforts. The CDER RM Program Team worked with each CDER office to develop an office file plan to specify which records are owned by specific offices, where these records are, and for how long the records should be maintained. Depending on the type of record, ownership may be defined at the office level, with the office director as the ultimate decision maker, or at the level of an individual role. Record custodians include any CDER employee that is responsible for the care and control of records in their possession and varies based on the process and the record type.

This MAPP lays the foundation to improve current RM practice by defining the RM governance model used in CDER. This MAPP describes RM roles, responsibilities, accountability, and processes to be used in managing records. CDER offices ensure their operating policies and procedures allow for effective management of CDER records in all formats, throughout their life cycles.

POLICY

- All records are the property of the federal government. All CDER employees are responsible for maintaining records in accordance with federal regulations and established business processes.

- The CDER RM Program manages, monitors, and measures CDER's compliance with CDER RM practices in accordance with National Archives and Records Administration (NARA) regulations and agency requirements.

- Each CDER super office director designates one or more RMC Member to support and represent RM activities in the super office.

- Each CDER super office director designates one or more Records Coordinator (RC) to facilitate RM activities in the super office. Additional CDER employees may be assigned to assist these designated RCs.

- Each CDER super office director or office director, or designee, notifies the CDER Records Management Program when an RC or RMC member is designated or changed.

- Each CDER office will include RM in their processes and policies to consistently manage their records in alignment with NARA regulations and agency requirements.

- CDER employees create and manage all records, including working files and emails that are records, as follows:

    1. Create and maintain records in electronic format whenever possible; creating or storing records in paper form is highly discouraged.
    2. Retain a record as a single unaltered copy, to avoid redundancy.
    3. Secure and protect records against unauthorized access, disclosure, alteration, and destruction to protect authenticity and reliability.
    4. Transfer and maintain records in the appropriate Electronic Recordkeeping System (ERKS), see MAPP 7600.11 (CDER Electronic Recordkeeping System) specified in the office file plan and accessible to all authorized parties upon completion (e.g., records are done/unchanging, the project or activity is closed, or the cutoff date has been met such as the end of year). Maintain records with related records to ensure searchability, long-term usefulness, and relevance.
    5. Archive and dispose of records in accordance with the records control schedule (RCS).

- CDER processes that do not adhere to the numbered requirements above, are revised to include applicable records management activities.

- CDER employees make available all records and information requested based on Freedom of Information Act (FOIA) and litigation requests and procedures, consulting with the FDA Privacy Office or the CDER Division of Information Disclosure Policy (DIDP), as appropriate.

- Departing CDER employees are not authorized to remove any records, or nonrecords unavailable to the public, without the Center Director's or designee's explicit permission.

- New, detailing, or recently transferring CDER employees are informed of RM responsibilities and provided annual agency RM training as part of the onboarding processes.

- CDER employees do not retain records beyond their retention period, except when a longer retention period is necessary. Examples include:
  1. The record is part of an open investigation, such as a legal hold or audit.
  2. An office knows the RCS will be modified and has a valid business reason to continue to hold the records.
  3. The RCS offers a flexible retention period, citing a minimum retention period but allows a longer retention period if required for business use.

- Nonrecords, such as reference copies and personal papers, are not stored with records, or in a CDER ERKS.

RESPONSIBILITIES

For the following roles, an individual may hold one or more roles.

CDER Center Director (or designee)

- Proactively supports the implementation and sustainment of the CDER RM Program.

- Meets with CDER leaders to promote effective RM.

- Facilitates the inclusion of RM activities, as well as mandatory agency RM training, in Senior Executive Service (SES)-level performance goals.

- Serves as the executive sponsor of the CDER RM Program.

- Provides leadership to encourage CDER employees to efficiently and effectively carry out RM activities to create an organizational culture that supports adherence to RM requirements.

- Evaluates recommendations provided by the CDER RMC at the CDER Executive Committee (EC), as appropriate.

- Ensures RM process and technology improvements are implemented by the Center to be in alignment with FDA policy and federal regulations, including the Government Performance and Results Modernization Act of 2010 and (Office of Management and Budget) OMB Circular A-130: Managing Information as a Strategic Resource.

- Coordinates with agency senior managers to ensure sufficient budgetary resources are available to successfully manage records in CDER, as referenced by NARA Criteria for Successfully Managing Permanent Electronic Records 3-16-2018.

Director, Office of Strategic Programs (OSP) (or designee)

- Assesses the current technical environment, policies, and solutions to enable RM within CDER.

- Makes RM policy and resource management recommendations to the CDER EC.

- Manages all practical aspects of the CDER RM Program including costs, time investment, RM requirements, and core CDER processes and functions.

- Ensures OSP/Office of Business Informatics (OBI) employees effectively manage the CDER RM Program.

- Directs OBI Information Technology (IT) teams to incorporate RM technical solutions throughout FDA's infrastructure.

- Allocates resources to serve on the CDER RM Program Team.

- Ensures that CDER IT capabilities are aligned with and are sufficient to support the RM Program requirements.

- Recommends the adoption of change to business operations and technology to carry out CDER RM duties.

CDER Executive Committee

- Sets strategic direction and makes high-level decisions about CDER RM.

- Allocates funds and employees for the CDER RM Program.

- Encourages the adoption of changes to business operations and technology to facilitate meeting CDER RM duties.

CDER Super Office Directors (or designees)

- Ensures all office employees take the annual mandatory agency RM training.
- Ensures RM-related training and duties are incorporated into annual employee Performance Management Appraisal Programs (PMAPs).
- Ensures RM policies and procedures are incorporated into existing and new processes and MAPPs, including documentation of record owners and custodians.
- Acts as the ultimate owner or decision-maker for records owned by his or her office. Delegates this responsibility as appropriate.
- Advocates to senior leadership for employee resources and support to enable appropriate RM within their office.
- Designates one or more RMC member(s) to collaborate with the CDER RM Program Team. Identifies one employee as the voting member for their super office.
- Designates one or more RCs to facilitate all RM activities for his or her office or super office and collaborate with CDER's ARLO and the CDER RM Program Team.
- Ensures the RC and the RMC member have knowledge of RM practices and resources, file plans, and an understanding of the RM life cycle.
- Ensures the RC and the RMC member receives appropriate training and support, assigning additional employees to assist, as needed.
- If an RC or an RMC member is unable to continue with his or her duties, ensures a replacement is appointed within 30 days.

Director, Office of Business Informatics (or designee)

- Ensures that CDER is compliant with NARA requirements for managing records.
- Coordinates with FDA Office of Information Management and Technology (OIMT) to align with Information Technology Strategic Plan for managing and maintaining information resources, as required by the Government Performance and Results Modernization Act of 2010.
- Incorporates RM requirements and functionality utilizing CDER ERKS.
- Reports progress of RM technology solutions to OSP Director.

- Maintains records that are stored in CDER ERKS and makes the systems and records available to the relevant parties.

- Proactively gathers relevant party and business-related RM requirements.

- Ensures IT solutions allow for adherence to RCS.

- Ensures IT solutions allow for user controls and policies to be established for system owners to know when records can be deleted based on the retention schedule; if controls and policies are not established or an exception occurs, contacts the CDER ARLO to determine if the record is eligible for deletion.

CDER RMC Chair

- Plans, chairs, and coordinates regular RMC meetings. Prepares and distributes agenda and minutes.

- Delegates responsibilities to council members.

- Ensures the principles of Equal Voice are followed by all members.

- Facilitates voting by a quorum of the voting members as defined in the RMC Charter.

- Identifies and creates working groups to address specific CDER RM issues.

- Maintains all electronic records related to RMC work.

- Completes NARA RM training as specified by CDER RM Program.

CDER RMC Member

- Understands the principles of RM and federal laws relating to RM, and applies this knowledge to office's information, records, file plans, documents, and associated processes.

- Informs or provides information to the CDER RMC Chair. Attends regular RMC meetings.

- Advocates for well designed, user-friendly Center-wide RM technologies, as recommended by the RMC.

- Reviews and recommends Center-level RM policy and expectations to ensure applicability for CDER program areas; assists in developing CDER RM policies and procedures.

- Ensures one vote is cast, on behalf of the super office, at relevant decision points.

- Establishes and maintains effective working relationships with office employees, RMC members, and the greater FDA community.

- Encourages office use of CDER ERKS and appropriate RM practices.

- Communicates with their office employees and other office RMC representatives to convey RM information and guidance.

- Coordinates efforts of the office RCs. Enables execution of RM improvements in their office. Consolidates and shares RC progress upon request.

- Liaises with the CDER ARLO and RM Program Team on RM-related questions and issues. Is responsive to CDER ARLO and RMC Chair requests and actions.

- Promotes RM awareness, training, and change management.

- Maintains an awareness of RM needs, including the records and associated processes and inventory updates, and the development of new business processes to incorporate RM, within the office.

- Completes NARA RM training as specified by CDER RM Program.

CDER RM Program Team

- Recommends vision, scope, objectives, and strategic plan for CDER RM Program.

- Coordinates with the OSP Director and EC as appropriate to obtain strategic direction to improve the RM Program throughout CDER.

- Assists the RMC Chair in conducting the RMC meetings and liaising with the RMC members. Provides information and obtains feedback and decisions from the RMC and EC.

- Understands and adheres to federal RM policies and procedures.

- Establishes continuous program improvement by addressing RM issues related to strategic planning, business process design, solutions development, and information security.

- Manages and escalates risks and issues across the CDER RM Program. Example, office processes do not include RM activities which may result in mismanagement of records.

- Communicates and coordinates with agency-level RM Program efforts and initiatives to ensure alignment and consistency of RM practices.

- Oversees the planning, implementation, operation, and management of the CDER RM Program.

- Provides recommendations, subject matter expertise, and day-to-day management and operations of the CDER RM Program.

- Coordinates with office RCs to maintain office file plans. Assists employees with discussions to clarify or confirm record ownership, as needed.

- Establishes CDER RM roles and responsibilities, MAPPs, processes, and standards.

- Coordinates CDER RM data calls, including vital records survey, performance metrics, self-assessments, and inventories.

- Oversees, develops, presents, and maintains CDER-specific RM training material for CDER employees.

- Provides guidance to CDER offices on scanning and digitizing records.

- Ensures records creation, maintenance, use, and disposition are in accordance with the Federal Records Act and other regulations.

- Regularly updates key relevant parties and leadership on CDER RM Program initiatives and metrics, including risks, issues, progress, integration issues, and dependencies.

- Provides guidance and management to the CDER RCs by facilitating regular and ad hoc RC meetings.

- Measures performance against current goals and objectives.

- Coordinates all CDER Regulatory Document Room RM activities.

CDER Assistant Records Liaison Officer (ARLO)

- Provides guidance and expertise to CDER employees on federal laws, regulations, and policy pertaining to RM.
- Leads, plans, implements, and manages CDER's RM Program to be in alignment with agency and NARA strategic plans.
- Provides RM guidance and expertise on CDER RM policies, schedules, file plans, technology, and procedures to CDER employees.
- Satisfies records inventories, surveys, and other data calls from the agency.
- Coordinates with FDA OIMT and the OBI for CDER RM planning and technology development to establish requirements for the retention of records in accordance with schedules.
- Works with record owners to draft new dispositions and records controls schedules for unscheduled records; coordinates FDA, NARA (and Government General Accountability Office (GAO) if necessary) approvals.
- Coordinates and communicates with the FDA Agency Records Officer (ARO) and other FDA employees to ensure CDER RM efforts are in accordance with the Federal Records Act, NARA, and agency regulations.
- Acts as a voting member of and participant in the CDER RM Council. Provides advice and guidance to RMC members.
- Coordinates with CDER RCs to ensure applicable RCSs and file plans are updated and accessible to employees.
- Facilitates the retirement and archiving of records owned by CDER.
- Works with RCs to assist departing employees, and their supervisors, to appropriately transfer and dispose of records prior to departure.
- Determines when a record in CDER can be retained longer than defined in the corresponding RCS.
- Determines where records owned by CDER can be stored.
- Coordinates with FDA Privacy Office and CDER DIDP, as needed, to ensure consistency with policies on RM.

- Works with Continuity of Operations (COOP) Coordinators to ensure CDER COOP records are appropriately identified and maintained.

- Obtains applicable RM certification through NARA.

CDER Records Coordinator (or designee)

- Acquires and maintains knowledge of FDA and CDER RM policies, procedures, technology, implementation plans and goals, and office file plans to share knowledge with office employees.

- Completes RM training as specified by CDER RM Program.

- Coordinates the transformation of their office's processes to incorporate RM practices and use of ERKS. Coordinates with their RMC member to address office changes and report on results.

- Acts as office point-of-contact and subject-matter-expert for office level RM questions and activities, escalating to the CDER ARLO and CDER RM Program Team when needed.

- Receives direction from the CDER ARLO and RM Program Team on strategic and tactical efforts to conduct within their office.

- Supports office employees to interpret and adhere to the office file plans, RCSs, and all FDA and CDER RM policies and processes.

- Advises departing and transferring employees, and their supervisor, in the transfer of their records prior to their departure, as per Attachment 3.

- Coordinates RM-related activities within their office including periodic cleanups, audits, and RM data calls. Advises the employees to manage their office records appropriately.

- Communicates critical updates in the CDER RM program to office employees.

- When RM activities require additional support, escalates the request to their supervisor.

- Identifies and communicates changes to the office file plan to the CDER ARLO. Helps office staff understand changes to record ownership, as needed.

- Assists the CDER ARLO develop new or revised RCSs when needed.

- Assists with RM training and communications, as needed.

CDER Employee/Record Custodian

- Follows the office processes that include RM activities by supporting the record owner and the record custodian in collecting and managing the records.

- Serves as a Record Custodian for their office's records if specified in their office processes.

- Serves as the Record Owner if responsibility is delegated by the Super Office Director or designee and documented in their office processes.

- Creates and manages records in an approved electronic format whenever possible. Limits and avoids the creation of paper records.

- Maintains records in an approved ERKS, as per CDER MAPP 7600.11, which promotes efficient retrieval.

- Completes the annual mandatory FDA RM training.

- Creates and manages the records necessary to document the agency's and CDER's official activities and actions in accordance with FDA and CDER recordkeeping requirements and the office file plan.

- Handles all CDER Regulatory Document Room regulatory materials and records in an appropriate manner to prevent loss or damage; returns CDER Regulatory Document Room materials and records immediately upon completion of their review.

- Avoids creating duplicates of records. Example, keeping multiple copies of a record in various locations or systems).

- Immediately reports any inadvertently removed, altered, or lost records to management and to the RC; reports damaged or lost CDER Regulatory Document Room materials and records to the CDER ARLO.

- Disposes of records in accordance with the RCS. Contacts CDER's ARLO or office RC for questions or exceptions on records disposition.

- Maintains personal papers and nonrecords separately from records. On a regular basis (at least annually) reviews laptops, non-systems of record, and personal

drives and disposes of duplicates, nonrecords, and personal papers that are no longer needed.

- Collaborates with appropriate relevant parties, office RCs, and CDER ARLO to address RM and retention issues.

- Coordinates with office RC(s) and supervisor to ensure records are transferred to the correct ERKS, prior to departing or transferring from their office.

CDER Supervisor

- Provides enforcement and oversight of their employee's RM activities.

- Ensures employees take appropriate RM training.

- Ensures RMC and RCs complete NARA RM training as specified by the CDER RM Program Team.

- Ensure processes exist for new staff to receive appropriate RM training.

- Ensures departing or transferring employees transfer records to an ERKS or other agreed upon repository before departing.

CDER Contracting Officer's Representative (COR)

- Provides the applicable RM training and information to contractors.

- Establishes and ensures adherence to appropriate RM procedures for contractors.

- Works with their office's acquisitions staff to include the appropriate RM language in contracts and task orders. (See sample NARA language in Attachment 5.)

- Acts as the record custodian. Maintains records created by current and past contractors until the disposition period ends.

PROCEDURES

CDER Office Processes

Many types of information and records are created and received by CDER, then used and maintained by CDER through the course of conducting business (e.g., regulatory review,

travel requests, guidance development). This results in the generation of records and nonrecords. Records must be dispositioned (transferred, deleted, or shredded) based on the appropriate retention schedule. Nonrecords can be destroyed immediately, or when no longer needed. (See Attachment 4 for graphic depiction of the record life cycle) These three phases are discussed in the first three sections below.

1. Records Life Cycle Phase 1: Create and Receive Records

A. Capture metadata and record attributes: Authors creating new records and others receiving records capture relevant document title and metadata (e.g., drug classification, fiscal year) based on their business unit to ensure consistent nomenclature is used.

B. Identify records and ownership:

a. Authors or recipients of information determine if the information meets the definition of a record per 44 U.S. Code 3301.

b. If determined to be a record, then authors or recipients of records determine record ownership. Record ownership may be designated by the Office Director, determined based on whether the organization created, acted on, received from an external source for action, or needs the record to document activities or decisions.

c. Authors or recipients of records may coordinate record ownership questions through the office RC or ARLO as needed.

d. Authors or recipients of records should document record ownership in the office file plan and process as appropriate.

C. Identify Records Control Schedule: Once identified as a record, the record owner must identify the appropriate RCS based on the record content.

a. See CDER Office File Plans: on the CDER RM SharePoint Online site or the FDA RCS intranet site.

b. If unable to identify appropriate RCS, contact CDER ARLO or office RC for assistance, or to develop a new RCS.

c. Treat unscheduled records as permanent records until a schedule has been approved by FDA and NARA.

d. File unscheduled records separately from records with an applicable RCS.

D. Organize: Once created or identified, the owner or custodian of the record secures it in an orderly manner, as per the RCS.

a. Organize common subject matter records together as follows:

- Arrange in a systematic (chronological or alphabetical) order, for easier future sorting.
- Group similar records with the same retention schedule and record date, including working files and emails that are records, and final records (See office file plan for details). Note: only retain working files as records if they contain substantive annotations or comments that add to a proper understanding of the FDA decision or action. (See Attachment 6.)
- Separate records from nonrecords (e.g., copies, reference materials).
- Apply appropriate office taxonomy or naming convention, to ensure records are identified consistently.

b. Coordinate with your office RC to ensure the record and associated information is included in the office file plan to maintain an inventory of office records.

2. Records Life Cycle Phase 2: Use and Maintain Records

A. Use: All CDER employees use records to conduct business processes. If applicable, identify and store convenience copies separately and destroy when no longer needed.

B. Maintain: The record owner and/or custodian stores all records in the appropriate CDER ERKS, as per CDER MAPP 7600.11, based on the business process, until its retention period ends.

a. Transfer records in their native file format that were developed in a collaborative system (e.g., SharePoint, shared drives, or email) to an ERKS with appropriate metadata upon completion (e.g., all records are unchanging, the project or activity is closed, or the cutoff date has been met such as the end of year). Note the records may still be "active" (e.g., needed, referred to, not superseded) when in an ERKS. Delete records from the originating collaborative system after the transfer, in alignment with approved business processes.

b. Store and maintain CDER Regulatory Document Room materials and records in an appropriate manner to prevent loss or damage; return CDER Regulatory Document Room materials and records immediately upon completion of their review.

c. Collaborate with CDER COOP Coordinators to ensure vital records are stored in accordance with the COOP Plan (See Staff Manual Guide (SMG) 3291.9 Records Management Essential-Vital Records).

d. Ensure records are readily available to appropriate relevant parties to avoid duplicate storage of records.

Note: Nonrecords (e.g., personal papers, duplicate copies, or reference materials) are not placed with records or in an ERKS.

C. Control: Periodically (at least annually) the following controls steps are taken:

a. The RM Program Team coordinates with and provides specific directions to the office RC to conduct a quality control (QC) review (i.e., audit/data call). This QC review requires each office to validate that only records are being maintained in an ERKS, completed records are transferred from collaboration tools to the appropriate ERKS, and expired records are disposed of (see Conduct Disposition below) in accordance with the office file plan.

b. Following these reviews, the office RC compiles the QC review results in the template provided by the CDER RM Program Team that is based on the office's current file plan and sends it to the CDER ARLO.

c. The RC and ARLO work together with the record custodians or owners to resolve RM problems as needed.

3. Records Life Cycle Phase 3: Disposition Records

A. Identify and conduct cutoff: As defined by the RCS, retention periods typically begin with the cutoff, rather than with the creation or receipt of a record. Cutoffs, or logical breaks in the record, are needed before disposition instructions can be applied. Cutoff of office records must occur in complete blocks, at regular intervals, to make it convenient when physically transferring records. Cutoffs can be:

a. Event driven: For example, when a case is closed.

b. Date driven: For example, at the end of fiscal or calendar year.

c. Combination of Event and Date: For example, at the end of the fiscal year, immediately after when the case is closed.

Record owners or custodians:

a. Identify the cutoff date.

b. Cutoff and group records based on RCS instructions and guidance.

c. Cutoff unscheduled records by select criteria (date, alphabetical) to make disposal as convenient as possible, once CDER has received the necessary authority from NARA.

B. Conduct disposition: Records maintained in an ERKS follow the disposition process as defined by the requirements of the particular system. Paper records and electronic records maintained outside of an ERKS (if indicated by the office file

plan) require CDER employee action to disposition based on the process listed below, in coordination with the Office RC as appropriate.

a. On a regular basis (at least annually), record owners or custodians review their individual laptops, non-systems of record, physical storage locations, and personal drives to identify records in the office file plan that are eligible for disposition.

b. Record custodians confirm the RCS with record owners and verify that the records are no longer needed for business purposes or are under a legal hold.

c. Record owners are required to be aware of legal holds that apply to their records and should maintain those records in accordance with the legal hold guidance. Questions are directed to the CDER ARLO.

d. Records that have met their retention schedule and are not under a legal hold, the record owner or custodian proceeds to permanently destroy the records (e.g., shred paper records, delete electronic records).

e. Upon completion of disposition, record owners send a list of specific records from the office file plan to be destroyed to the CDER ARLO as part of the disposition log to be tracked by the ARLO in the office file plan. If owners have questions, the CDER ARLO is available for assistance. The list will also identify any permanent records eligible to transfer offsite.

- If records are permanent, but eligible to be moved to an alternate location, the ARLO coordinates with the record owner or custodian to move the records offsite.

On a regular basis (at least annually), all CDER employees review laptops, non-ERKS, and personal drives and dispose of nonrecords and duplicates, with the assistance of office RCs.

C. Transfer records: Some of CDER's records, in accordance with their RCS, need to be transferred to the Federal Records Center (FRC) or the National Archives. Record owners or custodians work with their office RC and the CDER ARLO to complete the steps identified in FDA SMG 3291.1.

D. Maintain records beyond retention date: It may be necessary to hold records for longer than their planned retention period because of congressional inquiry, legal hold, or for a valid business need (e.g., reference material to support an ongoing regulatory review). Follow the steps below to maintain records beyond their anticipated retention date:

a. The record owner or custodian documents the business need to justify retaining records beyond their prescribed date to the CDER ARLO via email. In the request, the record owner includes a timeline for the extension, of up to three years.

b. The CDER ARLO reviews the request, consults with legal counsel if appropriate, and determines if the extension justification is appropriate.

c. The CDER ARLO replies to the request with his or her determination, either allowing for an extension of the specified timeframe or denial of the request with the appropriate rationale.

- If an extension is granted, the record owner or custodian maintains the ARLO's response along with the corresponding records for the designated extension period.
- If an extension is not granted, the record owner and custodian follow the disposition rules in the current retention schedule.

d. If additional extensions are required, the record owner or custodian initiates another request using the steps above.

4. Incorporate RM activities into CDER processes

To maintain records in accordance with the three phases discussed above, CDER offices must document and include the RM elements in all new and existing office process documents (e.g., standard operating procedures (SOPs), manuals, work aids, and document processing instructions). Process owners work with their office RCs to:

A. Identify the group or individual acting as the owner and the custodian (if applicable) responsible for the records associated with the process, particularly if the process is conducted by multiple organizations.

B. Document a list of records associated with the end-to-end process. This list should include inputs, working files, emails, and outputs.

C. Identify the applicable RCS for each of the records in the list.

D. Document relevant policies and requirements that may impact the RM procedures in the process.

E. Identify and define RM procedures associated with the process.

F. Identify required storage location and IT systems for the records at appropriate points in the process.

G. Identify essential or vital records related to COOP in coordination with the Office COOP Coordinator, as per SMG 3291.9.

H. Identify steps to dispose of records, in accordance with applicable RCS(s).

I. Identify appropriate step(s) to verify adherence to RM requirements.

J. Incorporate the information gathered from the previous steps in the process documentation.

Note: CDER employees may contact CDERRecordsManagement@fda.hhs.gov for assistance.

5. Transfer records prior to employee transfer or departure

Upon notification that an employee is transferring, departing, or going on detail, each CDER supervisor is responsible for ensuring that records in that employee's possession are appropriately transferred or disposed of prior to the employee's departure. The supervisor must coordinate with the employee and their office RC, and raise questions to the CDER ARLO as needed, to complete the following actions as appropriate:

A. Transfer any active work-in-progress information and knowledge to the agreed-upon repository or individual.

B. Transfer inactive records to an ERKS (as designated within the office file plan).

C. Dispose of copies and other nonrecords.

D. Coordinate with CDER ARLO on disposition actions needed for records (including emails) held past their retention.

Additional details to enable this process are available in the Departing and Transferring Employee Checklist. (Attachment 3.) Upon completion of these steps, the supervisor clears the employee in the current FDA employee exit system (e.g., eDepart), if applicable.

CDER RM Program Team Processes

1. **Manage the CDER RM Program:** These procedures are conducted to oversee the CDER RM Program to ensure RM priorities and initiatives are on track:

   A. The CDER RM Program Team provides regular updates to CDER leadership, including scope, risks, issues, progress, dependencies related to CDER RM activities.

   B. The CDER RM Program Team coordinates all CDER Regulatory Document Room RM activities.

   C. The OSP/OBI Office Director oversees the RM Program Team and the OBI IT Teams, to integrate RM technical capabilities into CDER ERKS.

   D. The RCs work with the CDER RM Program Team to facilitate completion of RM activities within their office.

   E. Per the RMC charter, the RMC meets regularly (at least quarterly) to:

      a. Review current and proposed RM policy.

      b. Raise and discuss CDER and office RM challenges and needs.

      c. Discuss RM Program updates, including agency and EC recommendations and direction.

d. Make recommendations, as needed, to the EC on policy changes and resource needs required to enable the CDER RM Program.

2. **Measure performance of the CDER RM Program:** The CDER RM Program Team:

   A. Establishes RM Program goals and objectives based upon regulatory requirements, standards, and best practices.

   B. Measures performance against current goals and objectives.

   C. Leads office RCs to gather and compile performance measures and metrics.

   D. Analyzes the CDER-wide operational benefits and challenges of RM annually.

   E. Provides the results of performance measures to the RMC and other leadership for their review annually.

3. **Modify the CDER RM Program:** Prior to making substantive changes to the CDER RM Program:

   A. The CDER RM Program Team develops recommendations for modifications to CDER RM policy and procedures.

   B. The CDER RM Program Team brings recommendations to the RMC for feedback.

   C. RMC members evaluate recommendations for RM and provide feedback to the CDER RM Program Team.

   D. The CDER RM Program Team brings RMC feedback and recommendations to the Director OSP for review and decision.

   E. The OSP Director makes recommendations to the EC for implementation and funding changes for RM initiatives.

REFERENCES

1. The White House, 2011, Presidential Memorandum on Managing Government Records.
2. The White House, 2016, Presidential Policy Directive 40, National Continuity Policy.
3. OMB, 2012, M-12-18. Managing Government Records Directive.
4. OMB, 2019, M-19-21. Transition to Electronic Records
5. OMB, 2022, M-23-07. Update to Transition to Electronic Records
6. E-Government Act of 2002, Public Law 107-347.
7. Government Paperwork Elimination Act of 2003, revised.
8. Government Performance and Results (GPRA) Modernization Act of 2010.

9. 1950 Federal Records Act, as amended, codified at 44 U.S.C. Chapters 31 (Records Management by Federal Agencies) and 33 (Disposal of Records).
10. OMB, July 28, 2016, Circular A-130: Managing Information as a Strategic Resource.
11. NARA, February 2018, 2018 – 2022 Strategic Plan.
12. NARA, March 16, 2018, Criteria for Successfully Managing Permanent Electronic Records.
13. FDA, 2008, SMG 3291.1 Records Management Policy.
14. FDA, 2018, SMG 3291.9 Information Resources Management – Records Management; Essential -Vital Records Management Policy.
15. FDA, 2022, CDER MAPP 4151.8, Equal Voice: Collaboration and Regulatory and Policy Decision Making in CDER.
16. FDA, 2017, CDER MAPP 7610.8, Electronic and Digital Signatures for Records Management.
17. FDA, 2015, CDER MAPP 7610.7, CDER Data Standards Program.
18. FDA, 2014, CDER MAPP 7600.11, CDER Electronic Recordkeeping Systems.
19. FDA, 2013, CDER MAPP 7600.10, CDER Master Data Management.
20. FDA CDER, 2018, CDER Records Management Council Charter.
21. CDER Records Management Program (SharePoint site)
22. OMB, 2019, M-19-21. Transition to Electronic Records.

DEFINITIONS

Agency Records Officer - responsible for overseeing the agency's records management program.

CDER Employee – For the purposes of this MAPP, includes CDER staff, fellows, grantees, interns, students, and contractors**.**

CDER Regulatory Document Room - Records storage facilities for CDER's regulatory documents established, maintained, and operated by CDER to track records through their lifecycle.

Contracting Officer's Representative (COR) – Employee who ensures that contractors meet the commitment of their contracts and assists contracting officers in managing their contracts.

COOP – Continuity of Operations (COOP) is a United States federal government initiative to ensure that agencies can continue performance of essential functions under a broad range of circumstances. (Presidential Policy Directive 40)

COOP Coordinator – Employee designated by each CDER office who serves as a key point of contact and is responsible for ensuring that office COOP information is accurate and that employees are informed about COOP procedures.

Cutoff – The breaking or ending of record files at regular intervals in accordance with RCS (e.g., at the close of a fiscal or calendar year or at the end of a case), to permit their disposal or transfer in complete blocks and, for correspondence, to permit the establishment of new files. (NARA Records Management Key Terms and Acronyms)

Disposition – Actions taken regarding records no longer needed for the conduct of the regular current business of the agency (36 CFR 1220.18). Disposition is a comprehensive term that includes both destruction and transfer of records to the National Archives (36 CFR 1226). Disposition instructions require the prior authorization of the Archivist of the United States and consist of two types:

Permanent Records – Records that have been determined by NARA to have sufficient value to warrant its preservation in the National Archives of the United States, even while it remains in agency custody. Permanent records are generally historically significant and are less than 5% of Federal records.

Temporary Records – Records that have been determined by the Archivist of the United States to have insufficient value (on the basis of current standards) to warrant its preservation by the National Archives and Records Administration.

Electronic Information System (EIS) - A system that contains and provides access to computerized Federal records and other information. (36 CFR 1236.2) An EIS includes the inputs and outputs that are generated, as well as the master files. The system may contain budgetary, fiscal**,** social, economic, scientific, technical, or program-related data and information, operated in support of agency programs and management responsibilities.

Electronic Recordkeeping System (ERKS) - An electronic system that captures, organizes, and categorizes records to facilitate their preservation, retrieval, use, and disposition.
Federal Records Center – Records storage facilities for Federal agencies established, maintained, and operated by the National Archives and Records Administration authorized under 44 U.S.C. 2907.

Freedom of Information Act (FOIA) – Law that allows for the full or partial disclosure of previously unreleased information and documents controlled by the United States government. The Act defines FDA records subject to disclosure, outlines mandatory disclosure procedures and grants nine exemptions to the statute (5 U.S.C. 552). The policy on disclosure of FDA records can be found in 21 CFR 20.20.

Governance – Establishment of policies, and continuous monitoring of their proper implementation, by the members of the governing body of an organization.

Nonrecord – 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 1220.18)

Office File Plan – In CDER, provides a summarized list of records owned and maintained by each office or division. This list includes the applicable RCS, file locations, file retention and disposition instructions, and other specific instructions that provide guidance for effective management of records, including vital records.

Personal Files – Documentary materials belonging to an individual that are not used to conduct agency business. Personal files are nonrecords and are not owned by the Government. Also called personal papers. (36 CFR 1220.18)

Quality Control –Systematic monitoring and evaluation to ensure that RM policies, procedures, and requirements are being met.

Record – The term records (A) includes all recorded information, regardless of form or characteristics, made or received by a Federal agency 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, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them; and (B) does not include (i) library and museum material made or acquired and preserved solely for reference or exhibition purposes; or (ii) duplicate copies of records preserved only for convenience. (44 U.S.C. Chapter 33, 3301)

Record Custodian – CDER employee who is responsible for the care and control of records throughout their retention period, including both physical possession (physical custody) and legal responsibility (legal custody), unless one or the other is specified. The custodian is responsible for ensuring the safety, timely availability, and proper disposition of the records in their custody. Custodians may or may not be record owners.

Record Cutoff Date – The date in which related records were cutoff in accordance with RCS to begin retention period.

Record Life Cycle – The cycle begins with information created or received by CDER, then used and maintained by CDER's business, and eventually transferred, deleted, or shredded, based on the appropriate retention schedule.

Record Owner – Employee or organization that owns and makes decisions on the records for which they are responsible for managing.

Records Control Schedule (RCS) – Provide mandatory instruction and federal authority by NARA for the retention, transfer, or the disposal, of records created, received, and maintained by the agency.

Records Management (RM) – The planning, controlling, directing, organizing, training, promoting, and other managerial activities related to the creation, maintenance and use, and

disposition of records to achieve adequate and proper documentation of federal policies and transactions and ensure effective and economical management of agency operations. (44 U.S.C. 2901)

Records Series – File units or documents arranged according to a filing or classification 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. (36 CFR 1220.18). All records fall into a records series, and each records series should be managed according to an appropriate records retention schedule. By managing related records as a group, records can be more efficiently preserved and disposed of.

Retention – The length of time a record must be kept (either in the office or in off-site storage) because it is needed for ongoing business, to document an action, or for statutory reasons. Note: This is also referred to as a "retention period." (36 CFR 1220.18)

Unscheduled Records – Records whose final disposition has not been approved by NARA on a SF 115, Request for Records Disposition Authority. Such records must be treated as permanent until a final disposition is approved. (36 CFR 1220.18)

Working Files – Documents such as rough notes, calculations, or drafts assembled or created and used to prepare or analyze other documents. Also called working papers. Working files are records (36 CFR 1222.12(c)) if both of the following apply:

1. They were *circulated* or made available to employees for *official purposes* such as approval, comment, action, recommendation, follow-up, or to communicate with agency employees about agency business; and
2. They contain unique information, such as *substantive annotations* or comments included therein, that *adds to a proper understanding* of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

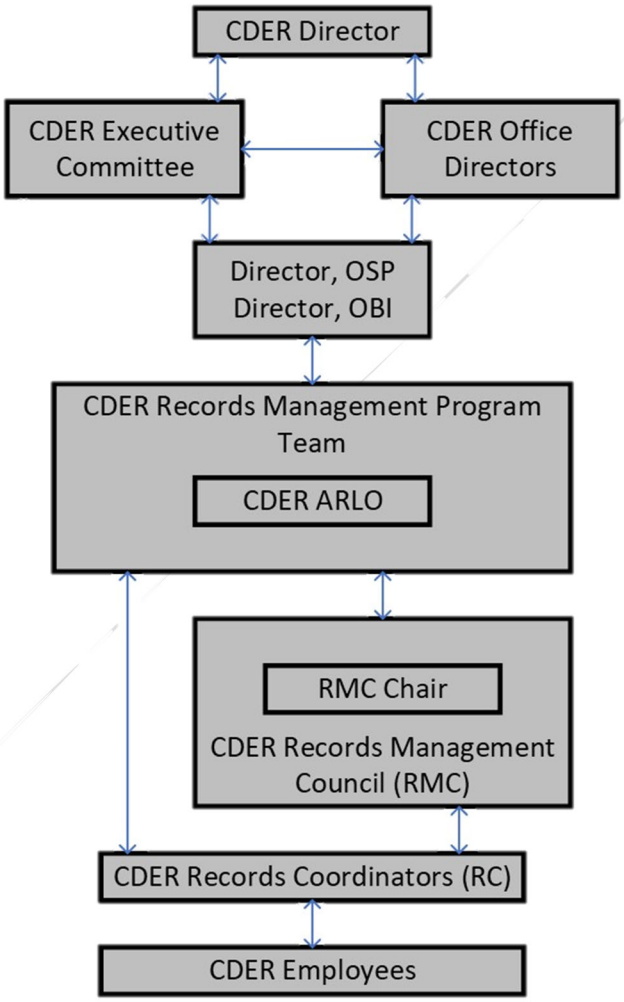
Effective Date	Revision Number	Revisions
10/18/19	N/A	Initial
8/16/21	N/A	Changed 'System of Record' to 'Electronic Recordkeeping System' throughout the document, as per NARA name change.
3/25/24	N/A	Pushed from Internal to Public posting. Minor updates to RM process. New artwork for Attachment 4.

ATTACHMENT 1: RM Communications Chart

This is intended to be a visual aid to indicate the relevant CDER Records Management parties that are described in the Roles & Responsibilities section of this MAPP.

There is no formal reporting requirement but rather this indicates communication flows and escalation patterns related to CDER Records Management program activities.

The following diagram depicts the communications flows between CDER Records Management relevant parties.



ATTACHMENT 2: CDER Office of Management Record Ownership

This chart contains some of the records common to all CDER offices. As of March 2019, the CDER Office of Management (OM) has agreed to maintain all CDER-versions of the records listed. Specificity is added in the Record Owner column where needed. As such, the other CDER offices do not need to keep copies of these records after submitting them to OM, or to include them as records in their office file plan.

Common Record Name	Description of Records	Records Control Schedule	Record Owner(s)
Employee award records	Time off, monetary, general, incentive, FDA/CDER honors, team awards	FDA-9241 Employee Incentive Award Records.	CDER OM
Personnel actions and associated documents and correspondence		FDA-9291 Notifications of Personnel Actions.	• CDER OM owns package submitted to FDA Office of Human Resources • CDER Offices own internal approval records (e.g., manager request of action)
Personnel adverse actions	Evidence of terminated employee issues for possible litigation	FDA-9272a Administrative Grievance, Disciplinary, and Adverse Action Files. Adverse action files.	CDER OM
Telework Agreements		FDA-9288a Telework/Alternate Worksite Records. Forms, requests, or applications to participate in telework/alternate worksite programs.	CDER OM
Performance Management Appraisal Program	Employee PMAPs	FDA-9223a Employee Performance File System Records. Acceptable performance appraisals of non-senior executive service employees.	CDER OM
Vehicle Logs	Usage logs of Government-owned motor vehicles	FDA-9561a Facility, Space, Vehicle, Equipment, Stock, and Supply Administrative and Operational Records.	CDER OM
CDER Manual of Policies & Procedures (MAPPs)		FDA-1310 Published Copy.	• CDER OM owns final record versions • Authoring CDER Offices own working files

ATTACHMENT 3: Departing and Transferring Employee Checklist

This checklist assists transferring and departing CDER employees and their supervisors to transition all records in the employee's possession before their departure. Employees should review the following locations where their records may be stored:

- Individual Hard Drive ("C" Drive)
- Network Drive ("M" Drive)
- MS Outlook (Email)
- Shared Drive
- SharePoint sites
- ECMS (Central repository)
- Paper storage (e.g., file cabinets, binders) in work or home office
- Other physical storage (e.g., CDs, DVDs, Iron Keys, external hard drive)
- Personal or government-issued computing devices (e.g., tablet, cell phone)

Any records that are in an approved CDER Electronic Recordkeeping System (ERKS) do not need to be reviewed.

Note: To remove any records, departing/transferring employees must have written permission from their supervisor.

Working files, such as rough notes, calculations, or drafts assembled or created and used to prepare or analyze other documents, are records if *both* of the following apply:

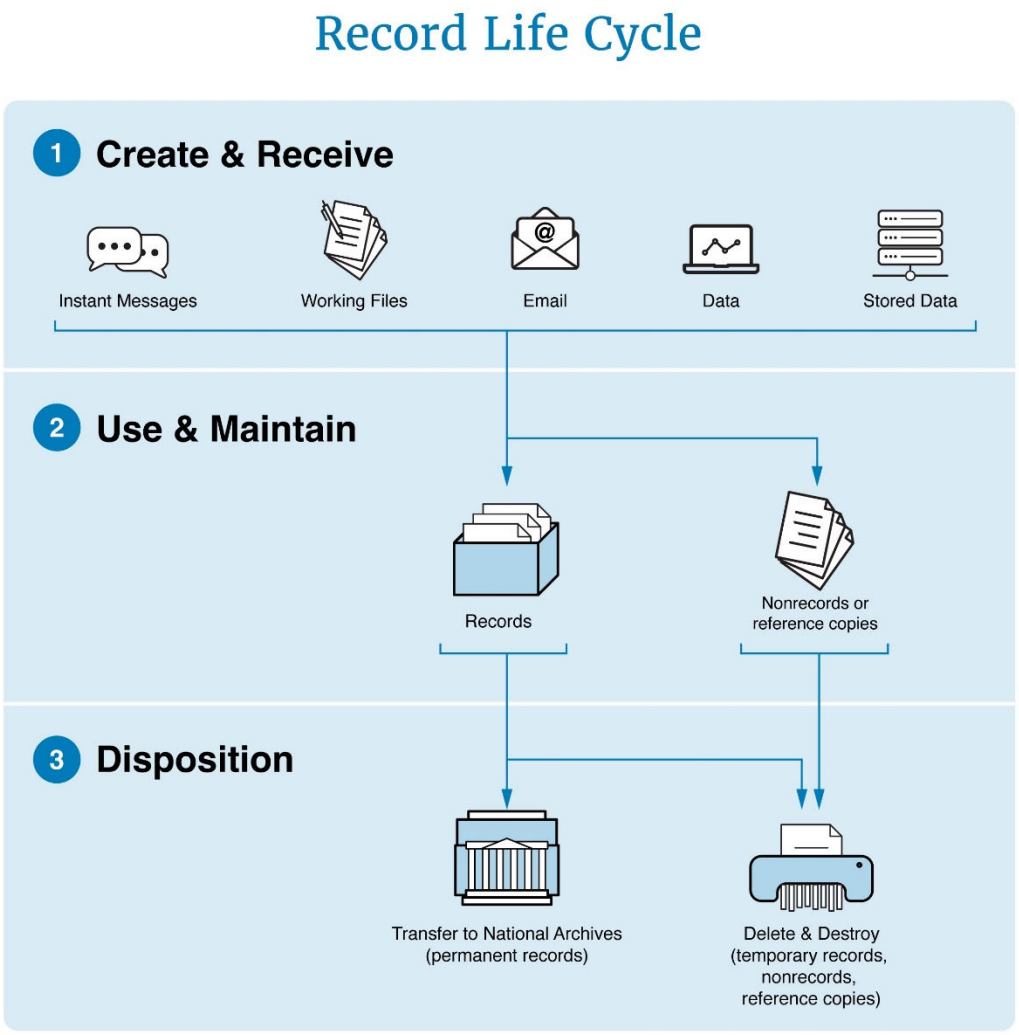
1. They were *circulated* or made available to employees for *official purposes* such as approval, comment, action, recommendation, follow-up, or to communicate with agency employees about agency business; and
2. They contain unique information, such as *substantive annotations* or comments included therein, that *adds to a proper understanding* of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities.

For questions on this activity or records, contact your office Records Coordinator or the CDER Records Management Program via CDERRecordsManagement@fda.hhs.gov.

Status ☑	CDER TRANSFERRING/DEPARTING EMPLOYEE CHECKLIST
Dispose of Nonrecords	
	1. Delete/destroy any *duplicates* of records that are already stored in a CDER Electronic Recordkeeping System .
	2. Delete/destroy any duplicates of a record in multiple media formats (e.g., paper copy, electronic file on shared drive, on CD, on Iron Key, Email, etc.).
	3. Delete/remove any personal information (e.g., music, pictures).
	4. Delete/remove reference materials (e.g., dictionaries, trade magazines) (see FDA-8900).
	5. Delete/destroy desk copies that **do not** have a barcode (all barcoded materials must be returned to the document room).
	6. Delete/destroy any personal and/or hand-written notes that were later transcribed into an official record.
Return Document Room Materials and Records	
	7. Contact DRTL-ALL@fda.hhs.gov to receive a list of any document room materials that are checked out in your name (if applicable).
	8. Return any checked-out materials with a barcode to the document room.
If Departing/Transferring Employee is a Supervisor	
	9. Delete/destroy files related to employees who left your purview more than one year ago AND do not have any open grievances or legal actions (FDA-9212).
	10. Destroy superseded records for current employees.
	11. Transfer current employee records and those records related to open grievances or legal actions to supervisor or replacement (if known).
If Departing/Transferring Employee has Records and Information under a Legal Hold	
	12. Collect records in one place (i.e., remove emails from Outlook and store with the other files), identify them as such, and transfer to supervisor or replacement (if known). To determine if a legal hold is still active, contact DRTL-ALL@fda.hhs.gov.
Transfer Records and Information	
	13. Transfer *in-progress* work and related emails to supervisor or replacement (if known).
	14. Move *completed* records and emails (in .msg format) from SharePoint, shared/personal drives, or Outlook to an approved CDER Electronic Recordkeeping System and delete from original storage location.
	15. Contact CDERRecordsManagement@fda.hhs.gov to transfer records to the National Archives, Federal Records Center, or other offsite storage, if applicable (see file plan).
For all Remaining Records and Information	
	16. Discuss each remaining record with your office Records Coordinator and supervisor or contact CDERRecordsManagement@fda.hhs.gov to determine if it can be archived in a CDER Electronic Recordkeeping System or destroyed because it has met its retention (see file plan). ▪ Ensure working drafts (36 CFR 1222.12(c)) with substantive changes/comments that add to proper understanding of the decision/action are maintained with the final record group for which they support.

ATTACHMENT 4: Record Life Cycle Graphic

This graphic provides an overview of the Record Life Cycle. Various types of information and records are created and received by CDER and are then used and maintained by CDER through the course of conducting business (e.g., regulatory review) which may result in the generation of records and nonrecords. Records must be dispositioned (transferred, deleted, or destroyed) based on the appropriate retention schedule, and nonrecords can be destroyed immediately or when no longer needed for reference.



ATTACHMENT 5: RM Language for Contracts

CDER contracts and task orders should provide clear legal obligations describing how the contractor must handle Federal records. CDER CORs and acquisitions staff must work together to add the appropriate RM language into contracts. NARA has developed the following language to be considered for inclusion into Federal contracts, as appropriate.

RECORDS MANAGEMENT OBLIGATIONS

A. *Applicability*

This clause applies to all Contractors whose employees create, work with, or otherwise handle Federal records, as defined in Section B, regardless of the medium in which the record exists.

B. *Definitions*

"Federal record" as defined in 44 U.S.C. § 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency 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, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.

The term Federal record:

1. includes [Agency] records.
2. does not include personal materials.
3. applies to records created, received, or maintained by Contractors pursuant to their [Agency] contract.
4. may include deliverables and documentation associated with deliverables.

C. *Requirements*

1. Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.
2. In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy

Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.

3. In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
4. [Agency] and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of [Agency] or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to [Agency]. The agency must report promptly to NARA in accordance with 36 CFR 1230.
5. The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records, or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the [contract vehicle]. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to [Agency] control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the [contract vehicle]. Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).
6. The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, contracts. The Contractor (and any sub-contractor) is required to abide by Government and [Agency] guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.
7. The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with [Agency] policy.

8. The Contractor shall not create or maintain any records containing any non-public [Agency] information that are not specifically tied to or authorized by the contract.
9. The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.
10. The [Agency] owns the rights to all data and records produced as part of this contract. All deliverables under the contract are the property of the U.S. Government for which [Agency] shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest. Any Contractor rights in the data or deliverables must be identified as required by FAR 52.227-11 through FAR 52.227-20.
11. Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take [Agency]-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.

[Note: To the extent an agency requires contractors to complete records management training, the agency must provide the training to the contractor.]

D. *Flowdown of requirements to subcontractors*

1. The Contractor shall incorporate the substance of this clause, its terms and requirements including this paragraph, in all subcontracts under this [contract vehicle], and require written subcontractor acknowledgment of same.
2. Violation by a subcontractor of any provision set forth in this clause will be attributed to the Contractor.

National Archives and Records Administration. (2019, July). *Records Management Language for Contracts.* Retrieved from https://www.archives.gov/records-mgmt/policy/records-mgmt-language

ATTACHMENT 6: Regulatory Review Working File Records

The official records produced as a result of the CDER regulatory review (e.g., IND, NDA, ANDA, BLA) process includes both **finalized documents** entered into an Electronic Recordkeeping System[1] (ERKS) (e.g., DARRTS, CDER Informatics Platform, RM Client) and **key working files**[2] that must be retained and entered into an ERKS (e.g., ECMS FDA-RM[3], CDER Informatics Platform). These key working files capture review, planning and scoping, communications, and the foundation and evolution of the review team's perspective, including differences in opinion between members of the team. Together, these final and working files comprise a complete picture of a regulatory review used to retrace the review team's initial plans and understanding, the review process, important considerations, and decision points. This document outlines the Center for Drug Evaluation (CDER) best practices for records management of regulatory review working files.

What Is a Regulatory Review Working File Record?

A Regulatory Review Working File Record is a developmental version of a document (e.g., reviews, correspondence, meeting minutes, checklists) created during the review process and documents unique information or decisions made during the review process. For example:

- *A substantially complete draft by the author(s). Substantially complete means the draft is ready to be moved up a level for review if indicated or checked into an ERKS.*
- Substantial comments and edits made during the document review and clearance process is checked into an ERKS.
- *Documentation of a communication between team members, such as a phone call or email, that captures a change in perspective within the team.*
- *Informatic data analyses (e.g., using JMP, SAS, JReview) produced during the review process. The data analysis can either be thoroughly described in review documents or by entering the scripts into an ERKS.*

What Is Not A Regulatory Review Working File Record?

A Regulatory Review Working File Record is not information in draft, or unfinalized, form used to facilitate a collaboration, conversation, or meeting. For example:

---

[1] See CDER Electronic Recordkeeping System (ERKS) - MAPP 7600.11.

[2] Per 36 CFR 1222.12(c), working files are records if: (1) They were circulated or made available to employees for official purposes such as approval, comment, action, recommendation, follow-up, or to communicate with agency employees about agency business; and (2) They contain unique information, such as substantive annotations or comments included therein, that adds to a proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities.

[3] DARRTS does not have the capability to accept working files or emails in .msg format at this time. DARRTS users are to enter working files into ECMS FDA-RM and reference the final review records in DARRTS. While not acceptable to PDF emails for RM purposes an exception has been made for emails going into DARRTS in order to enter the email message into the system. Duplicate records should not be retained in ECMS FDA-RM and DARRTS.

Substantially incomplete drafts of reviews (discipline or otherwise – e.g., integrated assessment) that may be shared between the review team members or between review team members and the management chain (e.g., Team Leader, Supervisor, CDTL, Signatory Authority).

Language copied from a review (finalized or otherwise) and placed into a letter template to allow the review team to collaborate on content and wording.

*Further, Correspondence templates initiated in preparation for a range of potential actions under consideration by the review team is not a record until a final direction is chosen and acted upon. At this point the draft with the non-chosen direction is a non-record. For example***:**

Preparing a Complete Response and Approval letter with similar information well in advance of the action date.

Best Practices in Review Working File Records Management

BEST PRACTICE
Document any change in perspective of a reviewer, the review team, or the signatory authority with:

1. Descriptive language in the related document;
2. A Memo-to-file of dissent; or
3. A Signature representing agreement.

Four common categories of working files that may be review working file records include (1) records related to communications with sponsors, (2) records related to internal communications, (3) records related to drafts, and (4) records related to data analyses. For each category, there are guidelines for capturing records in the ERKS.

1. Records Related to Communications with Sponsors
Below is a list of communication types and the corresponding best practices in records management.

T-cons or Phone calls with Sponsors
Enter whichever is applicable, Memo of T-con or a Memo to the application, into an ERKS and link it to the incoming submission, if applicable. The memo should capture the date, application number, product name, subject, participants, background, discussion, and action items.

Emails with Sponsors
Enter the email into an ERKS and link it to the incoming submission, if applicable.

Direct communications between FDA Review Staff and Sponsors

In rare cases and with supervisory approval, FDA review team members may communicate directly with sponsors regarding specific, limited issues related to their drug development programs. The FDA review team member documents the conversation in a memo to the application, enters it into an ERKS and provides a copy of that record to the appropriate FDA RPM for sharing with the rest of the FDA review team.[4]

2. Records related to Internal Communications

Review teams communicate throughout the review process across multiple channels. Document communications that result in a change in perspective within the review team and enter the documentation into an ERKS and link to the incoming submission, if applicable.

Non-User Fee Meetings

Non-User Fee meetings include internal meetings to prepare for User Fee meetings, team meetings, PeRC, and MPPRC. Capture main discussion points, recommendations, action items in the minutes. Enter the minutes into an ERKS and link to the incoming submission, if applicable.

There are two possible outcomes for records resulting from meetings:

1. If there is agreement on the final version in an ERKS, no further documentation is required
2. If there is dissent (e.g., between a reviewer and a team lead, or a specific discipline and Cross-Disciplinary Team Lead), it should be documented as a memo or review and linked to the meeting request

Internal Phone Calls

The content of an internal phone call is a record when it contains discussion or decision that is integral to understanding the process and/or outcome of a review. This may be captured in the review, a Memo of T-con, or a Memo to the application and entered into an ERKS. If applicable, link to the incoming submission. If a memo is generated, it should capture the date, application number, product name, subject, participants, background, discussion, and action items, if applicable.

Internal Emails

Internal emails are records when they capture a discussion or decision that is integral to understanding the process and/or outcome of a review. This may be captured in a review or by entering the email into an ERKS. If applicable, link to the incoming submission.

---

[4] Communications with FDA Review Staff are addressed in the *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* Guidance for Industry and FDA Staff - https://www.fda.gov/media/94850/download. Note - training expanded these practices to all communications, not just those during the IND stage.

3. Records related to Review Drafts
Drafts that are substantially complete and ready to be moved up a level for review should be retained and entered into an ERKS. Substantial comments and edits made during the document review and clearance process should also be retained and checked into an ERKS.

4. Records related to Data Analyses
Any data analyses that influenced a reviewer or team decision is a Regulatory Review Working File Record and should be captured in an ERKS. There are two options for recording data analyses; both should facilitate the re-running of analysis at a later date to recreate the same results.

Original Data Analysis Scripts
The scripts used to run the data analysis may be uploaded into an ERKS along with a reference or link to the relevant unchanged data set in the EDR (an ERKS). If the EDR data set is cleaned or manipulated to run the analysis, that revised data set should be captured in an ERKS.

Detailed Description of Data Analysis Performed
A brief description of the analysis can be written up and uploaded into an ERKS. This document should include all details necessary for the analysis to be recreated and re-run.