SMG 3291.13

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Records Management

FDA Electronic Information System Records Requirements (EIS-RR) Policy

Effective Date: 06/14/2024

1. Purpose

The purpose of this SMG is to establish the Food and Drug Administration (FDA) policy, responsibilities, and processes for determining if an FDA Electronic Information System (EIS) meets the NARA records management requirements for managing electronic records throughout their lifecycle, from creation or receipt, maintenance, use and preservation, through disposition of the records, in accordance with applicable Records Control Schedules (RCS).

As identified in the FDA Records Management Policy SMG 3291.1 and OMB Circular A-130, "Managing Information as a Strategic Resource", agencies are required to incorporate records management and archival functions into the design, development, and implementation of all agency information systems. FDA implements this requirement through the Enterprise Performance Life Cycle (EPLC) process, covering both the development and acquisition of new systems and periodic reviews of existing systems.

At present, the requirements outlined in this SMG are limited to systems within FDA, including 3rd party systems procured by the Agency. It does not cover government-wide shared systems containing FDA records that are not managed by FDA, such as financial management or travel management systems, or the Office of Personnel Management's centralized Electronic Official Personnel Folder (eOPF) system.

In addition, the requirements in this SMG do not apply to Outlook or collaborative platforms such as SharePoint and Teams per se, but any records created in these systems must be managed in accordance with records management requirements.

2. Background

The Federal Records Act of 1950, as amended in 2014, requires all Federal agencies to make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency. These requirements extend to all FDA electronic and physical records.

44 U.S.C. 3301 – Defines Federal records as "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".

44 U.S.C. 3102 and 36 CFR 1220.30 – Requires the head of each Federal agency to establish and maintain an active, continuing program for the economical and efficient management of the records of the agency. This RM program must provide effective controls over the creation, maintenance and use of records in the conduct of current business; and apply policies, procedures and techniques designed to improve the management of records. In addition, the FDA RM program must promote the maintenance and security of records deemed appropriate for preservation and facilitate the separation and disposal of records of temporary value.

Traditional records management principles as defined by the references above, are now being applied in a significantly changed, predominantly electronic landscape. Additionally, OMB Circular A-130, Managing Information as a Strategic Resource (paragraph 5.d.(5)(d)) establishes that "records management functions and retention and disposition requirements be fully incorporated into information life cycle processes and stages, including the design, development, implementation, and decommissioning of information systems, particularly Internet resources to include storage solutions and cloud-based services such as software as a service, platform as a service, and infrastructure as a service."

As the federal government continues to move towards a wholly digital future – promising enhanced governmental accountability and public access to agency records - policy decisions at the highest levels have prompted agencies, including FDA, to adopt new electronic recordkeeping practices and systems, and to expand existing electronic recordkeeping capabilities. This movement to electronic records has been driven primarily by the joint issuance by the Office of Management and Budget (OMB) and the National Archives and Records Administration (NARA), of **OMB Memorandums M-19-21**, Transition to Electronic Records and **M-23-07,** Update to Transition to Electronic Records, which establish several requirements and target dates for agencies to move to electronic recordkeeping, to the fullest extent possible.

3. Authorities

- OMB Circular A-130, "Managing Information as a Strategic Resource"
- Federal Records Act of 1950, as amended
- 44 U.S.C. 3301, Definition of Records
- 44 U.S.C. 3102, Establishment of Program Management
- 36 CFR 1220.30, What are an Agency's Records Management Responsibilities?
- OMB Memorandum M-19-21, “Transition to Electronic Records,” June 28, 2019
- OMB Memorandum M-23-07, “Update to Transition to Electronic Records,” December 23, 2022
- EPLC Records Management Plan template
- EPLC Methodology
- NARA Universal Electronic Records Management Requirements, v.3, June 2023
- 36 CFR Part 1236, Electronic Records Management
- NARA Bulletin 2015-04: Metadata Guidance for the Transfer of Permanent Electronic Records
- SMG 3291.12, “FDA Records Destruction Policy” (pending final approval)

- FDA Temporary Records Destruction Standard Operating Procedure (SOP)

- Federal Emergency Management Agency (FEMA) Federal Continuity Directive 1 (FCD1)

4. Policy

NARA regulation 36 CFR 1236.10 requires electronic information systems (EISs) used to store and manage Agency records to incorporate controls that will ensure the reliability, authenticity, integrity, and usability of Agency records for as long as the information is needed. In addition, they must preserve the content, context, and structure of the records.

These controls as defined by the regulation include:

1. Reliability: Controls to ensure a full and accurate representation of the transactions, activities, or facts to which they attest and can be depended upon in the course of subsequent transactions or activities

2. Authenticity: Controls to protect against unauthorized addition, deletion, alteration, use, and concealment

3. Integrity: Controls, such as audit trails, to ensure records are complete and unaltered

4. Usability: Mechanisms to ensure records can be located, retrieved, presented, and interpreted

5. Content: Mechanisms to preserve the information contained within the record itself that was produced by the creator of the record

6. Context: Mechanisms to implement cross-references to related records that show the organizational, functional, and operational circumstances about the record, which will vary depending upon the business, legal, and regulatory requirements of the business activity

7. Structure: Controls to ensure the maintenance of the physical and logical format of the records and the relationships between the data elements

An EIS that contains official records must also provide adequate controls and functionality to capture, identify, maintain, preserve, and ultimately allow for destruction or transfer of electronic records and data as needed.

To comply with these electronic records management requirements, FDA's RM policy requires that Centers/Offices manage and retain electronic records in either:

1. An electronic records management system/recordkeeping system (ERMS/ ERKS) such as the FDA Records Management (RM) Client (on the OpenText Documentum Platform), that has been designed specifically for the purpose of managing electronic records, following standard criteria to meet records management requirements and functionality. For example, the FDA RM Client is an electronic records management system (ERMS) which provides a compliant repository for storing and managing electronic records and provides built-in functionality to facilitate the transfer or disposal of records in accordance with their retention period. FDA staff can move electronic records, such as office documents, web content, publications, or audio-visual files, when they are completed, from shared drives or collaborative platforms into RM Client, where they are maintained and preserved as official records, **OR**,

2. An FDA electronic information system (EIS) that is designed primarily for FDA business purposes, not for managing records, but has been approved to create and house electronic records within them. These systems do not have built-in records management capabilities, however, ideally these systems can be configured and operated to provide sufficient controls and functionality to meet the requirements for managing electronic records in place.

To assist agencies with developing and maintaining a compliant EIS for electronic recordkeeping, NARA has issued Universal Electronic Records Management (UERM) Requirements: https://www.archives.gov/records-mgmt/policy/universalermrequirements, which identify the high-level programmatic and technical system requirements for managing electronic records throughout their lifecycle. The UERM are baseline ERM requirements derived from existing statutes, standards, NARA regulations, such as 36 CFR 1236, policy, and guidance and should be a starting point for agencies to use when developing system requirements.

Compliant records management, as required by FDA's SMG 3291.1, Records Management Policy, encompasses the full life cycle of records, which consists of three basic stages: 1) creation or receipt; 2) maintenance and use; and 3) disposition. To meet the FDA and NARA's minimum requirements for managing electronic records, an FDA EIS must incorporate the following features and functionality that enable management of the records throughout their life cycle:

- Ability to capture and identify records. For example, this can be done through assignment of a record ID, title, description, usernames, dates, and other metadata that can uniquely identify and retrieve the record. Attributes can be assigned by the system, manually by users, or a combination of both.

- Ability to apply a required retention period to the records, as defined by the FDA Records Control Schedules. This functionality may be built into the system or can be implemented manually (e.g., in the system documentation, procedures manual, instruction guidelines, or standard operating procedures).

- Application of adequate security controls to protect the records and restrict access based on authorization levels.

- Ability to maintain and ensure access to the records for as long as they are needed for FDA business and to meet retention requirements.

- Processes for identifying temporary records that have met their retention period and are eligible for disposal, as well as the ability to destroy the records with appropriate approvals, or to export permanent records for transfer to NARA.

- Ability to place a disposition hold on records that will suspend destruction of records needed to support litigation or other business purposes.

- Capability to generate standard and ad hoc reports for management to demonstrate controls and tracking of the system records (e.g., system, retention, or records activity).

Further details about these functions are discussed in Section 5. Requirements, below.

In many cases, particularly with legacy systems, not all requirements can be designed or built into the system. But collaboration between the business/system owner, Records Management (RM), and Information Technology (IT), can enable a combination of processes and technologies to provide necessary metadata, security, and functionality to adequately meet the minimum requirements.

The FDA Enterprise Performance Life Cycle (EPLC) processes require Centers/Offices to incorporate records management functions into the design, development, and implementation of all agency information systems. Records Management is identified as a critical partner in the FDA EPLC process to ensure that records management requirements and functionality are identified and incorporated into the planning, design, testing, implementation, and operation of all FDA IT projects and information systems.

When developing or procuring new systems or software, or upgrading existing systems, business owners should work with FDA records management staff, and IT personnel to tailor final system requirements to ensure that the system provides adequate controls to effectively manage the electronic content and data within the system as official FDA records. Language should be incorporated into contracts to clearly define RM requirements and functionality to meet the minimum requirements for managing electronic records. The EPLC Document Library provides a Records Management Plan template that can be used to guide this process.

For existing FDA systems, the business owner and system administrator, working with Center/Office Assistant Records Liaison Officers (ARLOs) and RM staff must

conduct an analysis of the system for these requirements when performing the mandatory periodic operational reviews (i.e., Authorization to Operate (ATO) reviews). If they can determine that a system can enable a combination of processes and technologies to provide necessary metadata, security, and functionality to adequately implement the minimum capabilities for managing electronic records, whether configured into the system or manually applied, a business system can be qualified as meeting FDA EIS-RR.

5. Requirements

A. Identifying and Managing Records in an EIS

Each FDA Center/Office must identify and track all records maintained in an EIS and coordinate with records creators/custodians and system owners to ensure electronic records meet records management requirements. Documentation that explains how records are managed must be maintained for any system supporting electronic records management as described in 36 CFR 1236.26, What actions must agencies take to maintain electronic information systems?.

Electronic records housed in an EIS must be easily accessible and must continue to have usability throughout their lifecycle in accordance with the business need and retention requirements.

The system owner must ensure records are collected, organized, and categorized to facilitate their preservation, retrieval, use, and disposition.

Systems that house FDA electronic records must:

- Ensure records provide authoritative evidence of the organization's work (functions, policies, and procedures) and must comply with FDA/Federal/NARA Records Management (RM) requirements.
- Ensure that there is a process in place to support the preservation and dispositioning of permanent records and their associated metadata for each system.
- Allow searching/retrieval on records content, metadata, and assigned subject categories (using controlled vocabulary) or keywords.
- Include metadata to support retention details by identifying records based on retention schedules and disposition instructions, electronically, if possible.
- Have the capability to render records immutable/unchangeable once they are declared a final record.

Records must be in a useable format for their required lifecycle.

Centers/Offices may store and maintain electronic records in FDA approved cloud-based systems that are FedRAMP certified by the Office of Digital Transformation through the Authorization to Operate (ATO) process. FedRAMP certification provides a standardized approach for ensuring security and protection of federal information using cloud services and is a federal requirement for all Federal records stored in the cloud. (Centers/Offices should contact their Information Systems Security Officer for further information.)

B. Retention of Records

Systems that house FDA electronic records must:

- Capture record series details and retention requirements and ensure that this detail is retained and accessible whether electronically or manually.
- Have the ability to flag records after their retention schedule expires.
- Have the ability to apply a legal or administrative hold and allow records put on hold to remain unchanged and in the same location, until the hold is lifted.
- The system owner must have a strategy to maintain records as required by retention schedules, as systems are updated or migrated to newer systems.

C. Disposition of Permanent and Temporary Records

An FDA EIS that houses FDA records of permanent value must identify, manage, and properly store the permanent records for later transfer to NARA. The system owner must work with their ARLO to ensure a method is in place to support the long-term retention of permanent records, with appropriate metadata, until they are eligible for transfer to NARA, typically after 20-30 years or more. Permanent electronic records to be transferred to NARA must include a minimum set of metadata elements as prescribed by NARA's Bulletin 2015-04, Metadata Guidance for the Transfer of Permanent Electronic Records.

Each EIS that houses temporary records must be monitored to identify records that have reached the end of their retention period and are no longer needed. Records that have met their retention period and are not on legal or administrative hold must be disposed of following instructions specified in the applicable FDA Records Control Schedule (RCS) and SMG 3291.12, "FDA Records Destruction Policy" (pending final approval) and the FDA Temporary Records Destruction Standard Operating Procedure (SOP). Electronic records within an EIS must be disposed of in a manner that protects sensitive, proprietary, or national security information.

D. Audit Trail of Records

The ability to track and audit records housed in an EIS is critical. The system must have the capability to provide an audit trail for its contents and activities, including changing the level of access, changing the record content or metadata, creating new records, reporting, or changing the location of the record. The audit trail provides evidence of the authenticity and reliability of a record to ensure full and accurate representation of any transactions or activities.

The EIS must:

- Create and maintain an audit trail for all records activities.
- Provide access to audit trail information at the fully detailed level (e.g., each individual record access, including record identifier, time, date, and user) with all transactions.
- Provide summary reports of audit trail information (e.g., number of accesses).
- Manage audit trail information (e.g., number of accesses, details of individual record retrievals, attempts to delete a record, etc.) so that it can be accessed as a record.

E. Security

Records must be protected throughout their lifecycle from unauthorized addition, deletion, alteration, use, and concealment. Each EIS must have appropriate security to ensure protection of the records throughout their entire lifecycle. Controls must be in place to:

- Prevent unauthorized access, modification or deletion of records including their metadata.
- Allow for review and monitoring of access rights and permissions.
- Allow for access rights changes.
- Ensure the usability of the records it creates for their business needs throughout the records lifecycle.

F. Essential Records

The system owner must have a method in place to identify and manage any records deemed essential. Essential Records should be identified and concurred with by the Center/Office ARLO and the Agency Essential Records Officer within the OEMS/Division of Information Governance (DIG) Records Management Team (RMT).

Essential Records as defined by the Federal Emergency Management Agency in Federal Continuity Directive 1 (FCD1) are: 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 legal and financial requirements.

G. Decommissioning of Systems

When a system containing electronic records is planned to be decommissioned or replaced, the system owner must coordinate with the ARLO and/or RMT to ensure all active records are identified and migrated, where applicable, to the approved new or replacement system. Inactive records that do not need to be migrated to a new or replacement system can be transferred to their program office official recordkeeping system for the remainder of the retention period. Records cannot be deleted from the decommissioned system until the successful migration of records to the new system has been completed and validated.

H. Compliance

If a Center/Office EIS cannot meet all the above requirements, the system/business owner must work with RMT and the Office of Digital Transformation (ODT) to determine what minimum requirements can be met and evaluate and mitigate the risks to the extent possible. At a minimum, a Records Management Disposition Plan must be developed to address retention and disposition of the system records. A mitigation could be to move the records into a system such as RM Client or another appropriate ERKS as soon as the records are inactive (i.e., not needed for day-to-day business).

6. Roles and Responsibilities

Roles and responsibilities outlined here are specific to this SMG. Additional and more comprehensive RM responsibilities are identified in SMG 3291.1, FDA Records Management Policy, including overall records management responsibilities for the FDA Records Officer (RO) and Center/Office ARLOs.

A. FDA Chief Information Officer (CIO) or designee within the Office of Digital Transformation (ODT)

The CIO, ODT is responsible for coordinating with RMT to ensure the incorporation of records management into the broader information resources management framework. The CIO will:

- Work in conjunction with records management as a critical EPLC partner to ensure the EPLC process incorporates records management principles and policies.

B. FDA Records Officer (RO) or designee

The FDA RO, with support from designated staff within RMT, is responsible for:

- Developing and disseminating FDA policies and guidance for managing electronic records in electronic information systems throughout their lifecycle in compliance with Federal regulations and NARA requirements.

- Assisting business owners and system developers with records management considerations as part of the EPLC process.

C. FDA Center/Office Directors

- Ensure that their Center/Office's Records Management program supports FDA and Federal Records Management requirements, policies, mandates and guidance for managing electronic records in electronic information systems.

D. Center/Office Agency Records Liaison Officers (ARLO)

- Work with Center/Office business owners to support the management and preservation of records housed in Center/Office electronic information systems in compliance with FDA policies and Federal requirements as outlined in this SMG.

7. Glossary

For full definitions of records management terminology used in this SMG, see the **FDA Records Management Master Glossary**

8. Effective Date

This guide is effective on June 14, 2024.

This policy does not supersede any other applicable law or higher-level Agency directive or guidance policy.

9. Document History - SMG 3291.13, "FDA Electronic Information System Records Requirements (EIS-RR) Policy"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/13/2024	N/A	OEMS/DIG/RMT	Tiffany Branch, Director, OEMS