SMG 3291.1

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Records Management

FDA Records Management Policy

Effective Date: 09/02/2022

1. Purpose

The purpose of this Staff Manual Guide (SMG) is to establish principles, standards, responsibilities, and requirements for managing Food and Drug Administration (FDA) records, regardless of format, to ensure compliance with applicable Federal laws, regulations, policies, and guidance, as well as related Department of Health and Human Services (HHS) and FDA policies. It provides the framework for records management program guidance and operating procedures for managing records throughout their lifecycle, from records creation or receipt, through maintenance and active use of the records for FDA business purposes, through storage of the records in a formal record-keeping system for the length of the authorized retention period, through disposition of the records by way of destruction or archiving, whichever is appropriate. 1

2. Background

The Federal Records Act of 1950, as amended, requires all Federal agencies to make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency.

[1] This document does not address the supplemental preservation requirements for records associated with litigation, investigations, and audit matters.

Federal records are defined in 44 U.S.C. 3301, 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".*

The head of each Federal agency, per 44 U.S.C. 3102 and 36 CFR 1220.30, is required to establish and maintain an active, continuing program for the economical and efficient management of the federal records of that agency. This records management (RM) program must provide effective controls over the agency's records throughout their lifecycle and apply policies, procedures and techniques designed to improve the management of records.

In the 21st century, traditional records management principles are now being applied in a significantly changed, predominantly electronic landscape. 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 was spearheaded primarily by the requirements and target deadlines established in the OMB Memorandum M-19-21, *Transition to Electronic Records*, issued in June 2019, which are incorporated into this SMG. Most FDA records are already electronic and new agency initiatives, such as those relating to the digitization of analogue records, means the agency's electronic footprint will only increase. At the same time, the FDA must also stay abreast of the many new types of electronic records, including, for example, those associated with social media accounts, collaboration platforms, and instant messaging. FDA personnel must keep this changed landscape in mind when carrying out their work activities that may involve federal records, at any point in the records' lifecycles.

In response to these many changes, the FDA has established program policies and guidance in this SMG that support consistent and compliant records management of all FDA records, regardless of format. This SMG expands the scope of RM program policies and procedures to address, for example, NARA requirements for managing cloud-based records, electronic messaging, social media, and other electronic forms of records and information. Other Agency electronic records management initiatives include, but are not limited to, implementation of an FDA-wide Electronic Records Management System, also known as Records Management (RM) Client built on the Documentum platform, and development of standards and requirements for digitization of physical documents.

3. Authorities

- Federal Records Act of 1950, as amended (44 U.S.C. Chapter 29, Chapter 31, Chapter 33)
- 36 CFR Chapter XII, Subchapter B, Parts 1220-1239, "Records Management"
- HHS OCIO-PIM-2020-06-004, v. 2.0, "HHS Policy for Records Management", May 28, 2020
- HHS OCIO-PIM-2020-06-005, v.2.0, "HHS Policy for Implementing Electronic Mail (Email) Records Management", May 28, 2020
- Presidential Memorandum, Managing Government Records, November 28, 2011
- OMB Memorandum M-19-21, Transition to Electronic Records, June 28, 2019
- FDA SOP 600-04, FDA Telework Program Policy, January 7, 2016
- OMB Circular A-130, Managing Information as a Strategic Resource, 2016
- National Archives and Records Administration, Universal Electronic Records Management Requirements, 2020
- SMG 3251.12, Information Systems Security and Privacy Policy, February 7, 2020, and addendum 3291.12a, Information Systems Security and Privacy Guide, v. 1.2, September 27, 2019 (internal link only)
- FDA Social Media Policy, November 2015
- Records Management Guidance for FDA Social Media Content
- SMG 3215.2, Archiving and Unpublishing Web Content Policy, March 23, 2017

4. Scope

This Policy applies to all FDA personnel who have access to FDA supported facilities or FDA information, systems, or resources. As used in this SMG, "FDA personnel" applies inclusively to all civilian government employees, contractors, political appointees, local or foreign government exchange program participants, Commissioned Corps personnel, guest researchers, visiting scientists, fellows, interns, volunteers, or any other non-government employees.

The policies established in this SMG apply to the lifecycle management of all records created or received while conducting Agency business, regardless of the format, medium, or technology platform (i.e., paper, electronic, microfiche, photographic, telephone records, social media, electronic messaging, audio, video, or other).

Nonrecord materials and personal papers are excluded from the definition of official records and do not need to be managed according to this policy. See the FDA Records Management Master Glossary for complete definitions and examples of these materials.

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

5. Policy

A. FDA Records Management Programs

It is FDA policy to preserve all official records, regardless of format, in accordance with applicable statutory and regulatory requirements, and to promote access to information by staff, partners, and the public, as appropriate.

Each FDA Center or Program Office is required to implement and maintain a records management program that meets the minimum requirements outlined in this SMG. Additionally, Centers/Offices may choose to develop and implement supplemental guidance and procedures specific to their programs that are consistent with these policies. The FDA Agency Records Officer (ARO) and Records Management Team (RMT) in the Office of Operations, Office of Enterprise Management Services (OC/OO/OEMS) direct the Agency level records management program and coordinate with the Center/Office Assistant Records Liaison Officers (ARLOs) to ensure consistent policy and practices.

As required by federal regulation (36 CFR 1220.32), the FDA's records management program must provide policies and procedures that ensure that:

1. records documenting Agency business are created or captured;

2. records are organized and maintained to facilitate their use and ensure their integrity throughout their active use and their authorized retention periods;

3. records are accessible and easily retrievable in a usable format for as long as needed to conduct Agency business;

4. legal and regulatory requirements, relevant standards, and Agency policies are followed;

5. records, regardless of format, are protected in a safe and secure environment that comply with FDA security requirements, and removal or destruction is carried out only as authorized in NARA-approved Records Control Schedules (RCS); and

6. continuity of operations is supported by an essential records program.

The FDA records management program encompasses the life cycle of records while they are in Agency custody, which consists of three basic stages: 1) creation or receipt (see section 5.B); 2) maintenance and use (see section 5.C); and 3) disposition (see section 5.D), as defined in 44 U.S.C 2901 (see definition of Records Management).

Centers/Offices must institute processes and technology that will enable Agency records to be created and managed in accordance with FDA and other Federal records management policies, in an electronic format to the greatest extent possible, for their full lifecycle. In addition, they must develop and implement plans, as NARA guidance becomes available, to achieve the transition from hard-copy and other analog formats to an electronic format. See, e.g., SMG 3291.10, "FDA Temporary Records Digitization Policy," for FDA's policy and guidance on converting temporary paper records to digital format.

B. Creation and Receipt of FDA Records

FDA personnel must ensure that FDA records contain "adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions" of the FDA. These records must be "designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the Agency's activities" (44 U.S.C 3101).

Each Center and Program Office creates, receives, and maintains administrative and programmatic or mission-specific records for their organization in the course of doing business. FDA staff must ensure the authenticity, integrity, reliability , and usability of their records for the length of their authorized retention period.

Federal records can be created and received in various formats, such as documents, spreadsheets, presentations, electronic messages, audio and video files. While they are in development or actively being used for FDA business purposes, these federal records can be stored in databases, maintained in physical office spaces, or in electronic environments such as email applications (e.g., Microsoft Office 365), network drives, collaborative applications, and

information systems. However, it is important to understand that not all electronic applications are appropriate for storage of completed official records. When a project or activity is completed and the associated records are finalized, they should be moved to an official recordkeeping system. See more in section 5.C on storage and protection of records.

Records Ownership

Throughout the records lifecycle, FDA records are the property of the Federal government, not the property of FDA personnel to which this SMG applies, and they may not be removed from FDA without proper authority. FDA ownership applies to all records regardless of media, whether they physically reside at FDA and/or other locations or are electronically preserved in electronic repositories at records storage facilities or cloud environments.

C. Maintenance and Use

FDA personnel must organize and maintain records so that they can be readily located and retrieved when and where needed, in a usable format, for as long as needed, to support FDA's programmatic, administrative, fiscal, legal, operational, and historical needs. This pertains both to the period when records are in active use for FDA business purposes and throughout their authorized retention period, whether in physical storage or an electronic recordkeeping system. Tools for maintaining and using Agency records include office records inventories and file plans, or similar indexes and tracking systems, all of which are discussed below.

Procedures should include controls for the safe handling and protection of records against loss, or unauthorized additions, changes, or deletion. Records should be maintained separately from nonrecords and personal files.

Records Inventories

Centers/Offices must conduct periodic records inventories to gather information about the records in their custody so they can efficiently locate and manage their records, dispose of temporary records, and transfer permanent records to NARA, in compliance with this SMG. Records inventories also allow Centers/Offices to identify and describe their records, including essential and permanent records, to ensure retention schedules are applied appropriately, and to assist in identifying unscheduled records and nonrecords. Results of inventories are documented in Center/Office file plans.

File Plans

RMT must coordinate with Center/Office ARLOs to create and maintain a centralized file plan to enhance access to and usability of current Agency records, for preservation of archival records, and for prompt and systematic

disposition of permanent and temporary records according to the appropriate FDA RCS. A file plan should include at a minimum, the Center/Office name, the Title (Name of Records), Record Series Number, Record Series Title, Record Description, Disposition Type, and Disposition Instructions. Per HHS Policy for Records Management, section 6.1.4.1, FDA Centers/Offices must standardize file arrangement systems, filing procedures, and filing techniques of records. These standards should follow procedures used within their organizations.

Storage and Protection

All FDA personnel using and maintaining records (physical or electronic) must provide protections and security levels commensurate with the sensitivity and nature of the records being used or stored to comply with FDA and other federal information systems security and privacy policies.

FDA records storage facilities and repositories (physical or electronic) must incorporate adequate controls to prevent unauthorized access, modification, or destruction of FDA records. Centers/Offices must establish processes to ensure that only authorized users have access to the records and recordkeeping resources that they need. Access rights should be reviewed regularly to verify continuing need and updated as needed. Offsite facilities used for storage of FDA records must meet the requirements of 36 CFR Part 1234 Subpart B and be approved by NARA (see section 5.D). Official records should never be stored in unapproved records storage facilities, or left abandoned in unattended areas in the Agency or FDA-leased warehouses.

As a general rule, temporary electronic records are retained by FDA for their full lifecycle. NARA regulations (36 CFR 1236.10) require that FDA electronic information systems used to store and manage Agency records must incorporate controls that will ensure the reliability, authenticity, integrity and usability of Agency records for as long as the information is needed, and preserve the content, context, and structure of the records. Alternatively, these controls may be integrated with an FDA recordkeeping system that has the same functionality built into the application, such as RM Client/Documentum. It is important that staff understand that some FDA electronic applications and tools, such as SharePoint Online and Outlook, while commonly used on a daily basis to facilitate business activities, do not have adequate controls for storing and maintaining official records for their required retention period. Completed records must be moved from these applications to an official recordkeeping system following Agency and Center/Office guidance.

Reporting Loss or Deletion of FDA Records

Upon discovery of any event resulting in unauthorized access, alteration, alienation, loss, or deletion of FDA records, FDA personnel must notify their Center/Office ARLO and the FDA Records Officer (RO) or designee immediately, and their Center/Office Information System Security Officer when appropriate. The FDA RO or designee will report the incident to NARA when required, in accordance with 36 CFR 1230.14. The ARLO or RO/designee must also notify the ODT Cybersecurity Infrastructure Operations Coordination Center at CIOCC@fda.hhs.gov immediately when the incident involves the loss/breach of FDA equipment or systems, or a Personally Identifiable Information (PII) breach.

D. Disposition

"Records disposition" is an overarching term that refers to different, possible activities that can be taken at the end of the record lifecycle, including:

- disposal of temporary records that are no longer needed for the conduct of business, by destruction or donation;
- transfer of temporary or permanent records to a storage facility for a specified retention period;
- transfer of permanent records to custody of the National Archives for continued preservation; or
- transfer of records from one Federal agency to another agency.

The primary tool for managing the disposition phase of Agency records is the records retention schedule, i.e., the FDA RCS and Center-specific Schedules. (See section 5.F below for more about scheduling records.) The RCS disposition instructions specify what is to be done with a record that is no longer needed to support agency business. They typically specify a "cutoff," meaning the point when the records are considered complete (e.g., end of fiscal year, end of project) and the minimum required retention period. The start of the retention period is based on the cutoff, not necessarily on the age or creation date of the record. For example, a contract file is an active record until the contract period has ended and all payments have been made, after which the file is cut off and the retention period starts.

Disposition of Temporary Records

Centers/Offices must transfer paper and other analog temporary records that are no longer sufficiently active to warrant retention in FDA office space, in accordance with an approved RCS, as soon as possible to a Federal Records Center (FRC) (see note below), an FDA-approved commercial records

storage facility, or other approved storage location, where they will be stored until eligible for disposal. FDA records must be stored in NARA-approved facilities that meet the requirements of 36 CFR Part 1234 Subpart B. See SMG 3291.11, "Transfers of Temporary Physical Records to Off-site Storage Facilities" (SMG is in final draft format and pending management approval), for detailed policy and guidance on transferring FDA records. See also, "SOP for "Transferring Temporary Physical Records to Offsite Storage Facilities" (revised October, 2021).

Centers/Offices must dispose of temporary records that have reached the end of their retention period and are no longer needed, following instructions specified in the applicable FDA RCS and SMG 3291.12, "FDA Records Destruction Policy and Procedures" (SMG is in final draft format and pending management approval).

If Centers/Offices elect to transfer temporary electronic records to the FRC, the transferring Center/Office ARLO will work with the RMT to initiate the transfer. Transfers to commercial offsite storage will be arranged by the Center/Office, following established procedures.

NOTE: Per the OMB M-19-21 Memorandum, after December 31, 2022, FRCs will no longer accept temporary paper/analog records for transfer; all records transferred to FRCs after that date must be transferred in electronic format. After the deadline, temporary paper and other analog records must be transferred to a commercial storage facility.

Disposition of Permanent Records

In keeping with the OMB M-19-21 mandate, all FDA permanent records will be managed electronically to the fullest extent possible, with appropriate metadata, for eventual transfer and accessioning to NARA in an electronic format.

FDA must offer permanent FDA records for transfer to NARA when the records are eligible, as specified in the applicable FDA RCS, or when they have been in existence for more than 30 years. If there is a continued business need to keep permanent records at FDA beyond the specified retention period, the FDA RO or designee must obtain written approval from NARA.

When transferring paper permanent records to NARA through December 31, 2022, or as otherwise specified by NARA, Centers/Offices should follow SMG 3291.13, "Accessioning Permanent Physical and Electronic Records into the National Archives", and "SOP for Accessioning Permanent Physical and Electronic Records into the National Archives" (both documents are in final draft format and pending management approval).

Electronic records must be transferred in accordance with the specifications and standards outlined in 36 CFR Part 1235, Subpart C, using formats and media that are acceptable to NARA at the time of transfer. Centers/Offices choosing to digitize paper permanent records for transfer, must convert and transfer the records to NARA, following NARA requirements and other direct guidance from NARA at the time of transfer (while awaiting NARA's issuance of formal regulatory standards in the future).

E. NARA-Approved Records Control Schedules

All FDA records must be listed and described in a NARA-approved RCS and must be disposed of, only as authorized by that schedule. FDA RCS provide mandatory instructions and authority on how long to keep records and when they can be destroyed, transferred to alternate storage or to an FRC, or submitted to NARA. Records without an approved RCS must be maintained indefinitely until a new schedule has been written and approved by NARA for use. Unless specifically required by statute or regulation, all records series in schedules submitted to NARA after December 17, 2007 are considered media neutral and apply to all records regardless of format or medium on which they are maintained.

FDA Centers/Offices develop RCS for their program-specific records for approval by NARA in accordance with 36 CFR 1225. The FDA RO or designee develop Agency-wide schedules and maintain a consolidated FDA RCS of all Agency-wide and Center/Office specific schedules. Where applicable and appropriate, a Center/Office may adopt use of another Center/Office-specific schedule for similar records in lieu of developing a brand-new schedule, for efficiency and to avoid duplication. FDA foreign offices may also need to use Department of State (DOS)/Embassy Foreign Records Disposition Schedules for joint FDA/Embassy records or when contracted services include maintaining official records in DOS/Embassy systems.

Program offices develop proposed new and revised schedules in coordination with their Center/Office ARLO and the FDA RO or designee, and obtain FDA internal review and clearances necessary prior to submitting the schedules to NARA for final approval. If legal guidance is required, the FDA RO or designee will work with the FDA Office of Chief Counsel (OCC) to resolve issues related to retention and disposition authority. Note that per 36 CFR 1225.20, FDA may need to obtain approval from the Government Accountability Office (GAO) for new schedules that propose retention of program records for less than three years, as well as deviations from GRS retentions (see section 5.M below) prior to final approval by NARA.

Each FDA Center/Office must regularly review their current RCS and update or create new schedules when unscheduled records are identified; or when

changes to program mission and business functions result in the establishment of new types of records, or the transfer or termination of records; or when business use of the records requires an increase or decrease of retention time.

FDA's Use of General Records Schedules

FDA must incorporate the applicable NARA GRS into the FDA RCS. New or revised GRS issued by NARA must be incorporated into the FDA RCS or otherwise disseminated to all FDA personnel within six months of the GRS transmittal.

As required by 36 CFR 1227.12, if FDA requires a different retention period than is outlined by the GRS, FDA must ask NARA for a variance, by submitting an SF 115, specifying the required retention period with justification for the deviation.

F. Records Management Training

The RMT, Center/Office ARLOs, and/or other designated staff must provide records management training to all appropriate FDA personnel, to ensure they are aware of their records management responsibilities, as required by 36 CFR 1220.34(f).

"New Employee Orientation (NEO)" and "Non-Employee (Scientist) Orientation (NESO)" are provided to all new FDA personnel within their first 30 days of duty. These briefings provide new employees and non-employees with an overview of FDA's records management requirements.

FDA Records Management Training is a formal, mandatory records management awareness training course that must be completed by all new FDA personnel covered by this SMG within 30 days of receiving the assignment from the FDA Learning Management System, and then annually, as a reminder of their record-keeping responsibilities with respect to FDA records. Email notifications will be sent to all FDA personnel requiring that they complete the latest version of the Records Management Training. Failure to complete the training by the deadline will result in loss of their FDA network access, until they complete the training.

Additionally, FDA Centers/Offices may require records management training specific to their Center/Office, provided through their ARLO and/or other designated staff. FDA and NARA also provide a variety of optional records management training for employees.

Incoming Senior Officials and Political Appointees must be briefed upon arrival, regarding the importance of appropriately managing records under their immediate control. Departing Senior Officials and Political Appointees must be briefed upon separation, on the appropriate preservation and disposition of

records, including email and social media accounts under their control, and obtain appropriate approval before removing copies of records. See SMG 3292.3a, “Records Management Guidance for New and Departing Senior Officials” (SMG is in final draft format and pending management approval) for additional guidance.

All FDA contract personnel covered by this SMG, who have access to FDA information, an FDA information system, protected health information (PHI), or personally identifiable information (PII), must complete the FDA Records Management training before performing any work under their contract. Thereafter, the contractors must complete annual Records Management training throughout the life of the contract. Contractors must also ensure subcontractor compliance with this training requirement.

G. Other Program Requirements and Guidance

Chain of Custody

Centers/Offices must follow an appropriate chain of custody process, such as the eDepart process, for records of departing employees, to ensure that records maintained by the employee during their tenure at FDA are accounted for and not improperly removed or destroyed. Personnel leaving their existing position within FDA or departing the Agency, must turn over all records (electronic and physical), artifacts, and other materials that may have been submitted for scientific review, to their supervisor, successor, or Center/Office document room, as appropriate, prior to departure. See SMG 3291.3, “Records Management Guidance for New and Departing Employees,” and SMG 3291.3a, “Records Management Guidance for New and Departing Senior Officials,” for more detailed guidance on the departure process as it relates to FDA records (both SMGs are in final draft format and pending management approval).

Essential Records

FDA Centers/Offices must support the FDA Essential Records Program in accordance with SMG 3291.9, “Essential Records Program,” in coordination with the FDA Essential Records Officer and Continuity of Operations (COOP) Program, to ensure that essential records, within their areas of responsibility, are identified, safeguarded, maintained, and updated as required.

Managing FDA Records When Teleworking

As telework becomes more common across FDA, employees must ensure they adhere to all FDA records management, information security, and safety policies and requirements, when working from home or other remote location, as specified in FDA SOP 600-04, FDA Telework Program Policy and the FDA

Telework Agreement. Requirements for properly managing and protecting FDA records and information while teleworking include:

1. Employees must use Government-Furnished Equipment, not personal equipment, when performing FDA work, and they must use the FDA Virtual Private Network (VPN) access when connecting to the FDA network and systems. Employees should maintain their work electronically on the FDA network to the extent possible, and must upload completed FDA records to their Center/Office official recordkeeping system.

2. Employees must safeguard all FDA records and information created or received while teleworking, including sensitive, Privacy Act, or proprietary information. They must protect all government records and data from unauthorized disclosure, access, alteration, damage, or destruction, by family members, and other non-FDA individuals, who may have access to their home or remote work location.

3. Printing is not recommended when teleworking. Extraneous materials printed while teleworking or working remotely must be destroyed appropriately so that the information cannot be recovered. Cross-cut shredding is recommended. Documents must not be placed in home trash or recycling bins.

6. Managing Electronic Records

A. Universal Electronic Records Management (ERM) Requirements

NARA regulations (36 CFR 1236.10) require that FDA electronic information systems used to store and manage Agency records must incorporate controls that will ensure the reliability, authenticity, integrity and usability of Agency records for as long as the information is needed, and preserve the content, context, and structure of the records. Alternatively, these controls may be integrated with an FDA recordkeeping system that has records management functionality built into the application.

To assist agencies with managing electronic records, NARA has developed Universal Electronic Records Management (ERM) Requirements that provide baseline standards for electronic records management systems and tools that are derived from their regulatory requirements, policy and guidance. The Universal ERM Requirements identify program and system requirements for compliant lifecycle management of electronic records, which incorporate features and functionality for:

- Capture – placing relevant information under records management control

- Maintenance and Use – managing records through their active stage

- Disposal – destroying temporary records that no longer have value in accordance with the applicable RCS

- Transfer – legal transfer of permanent records with enduring value to NARA

- Metadata – capturing identifiers that describe the context, content, and structure of the records

- Reporting – generating reports for further analysis or to demonstrate effective controls and compliance.

Systems that store FDA electronic records must also provide audit trails to track the use of records, changes made to access levels, updates to the records, and movement or duplication of the records.

B. FDA Approved Recordkeeping Systems

FDA Centers/Offices must manage and retain official electronic records in an approved FDA electronic recordkeeping system (ERKS), such as the FDA Records Management Client (i.e., Documentum), another FDA-approved records management application, or other FDA-approved electronic information system (EIS) or repository that meets the FDA EIS records requirements, which are based on NARA's UERMs. SharePoint Online is not an approved recordkeeping system, but may be used for collaboration and interim storage of electronic records. Centers/Offices must maintain a current list of their respective systems that contain electronic records. Electronic records managed in FDA electronic systems are retained and dispositioned according to the FDA records control schedules appropriate to the record content. Per NARA scheduling guidance, systems are not scheduled individually.

FDA electronic recordkeeping systems may be internal Agency-wide information systems or Center-specific systems (for example, the Agency Information Management System (AIMS) or CDER's Document Archiving, Reporting and Regulatory Tracking System (DARRTS), and also include government-wide administrative support systems or systems managed by external commercial providers (such as Concur travel system, Unified Financial Management System (UFMS), Electronic Official Personnel Folder (eOPF), and other systems that maintain FDA records in off-premise electronic repositories or cloud environments. Language must be included in contracts or terms of agreement regarding records requirements, such as ownership, access, retention, and migration of FDA-owned electronic records, information, and associated data that

is created, maintained, and stored on platforms owned by other government entities or third-party vendors.

Appropriate Center/Office management, as well as the FDA Office of Digital Transformation (ODT), must approve systems or devices used to store FDA electronic records, in compliance with policies established by the Chief Information Officer (CIO). Systems must be granted an Authorization to Operate (ATO) and software and storage devices must appear on the Master Approved Technology (MAT) list before they can be used.

OMB Circular A-130, "Managing Information as a Strategic Resource," requires agencies 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.

C. Email and Electronic Messaging Records

Users of FDA electronic mail (email) and electronic messaging resources are responsible for the retention and preservation of the messages that they create/send or receive, if they meet the definition of a Federal record (44 U.S.C. 3301). These responsibilities apply to all agency-administered email accounts assigned to a user, whether they use one or more email accounts for official business. Email and electronic messages are considered records when they are:

- 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.

Electronic messages include (but are not limited to) emails, chats, blogs, instant messaging, text messaging, voicemail, and other messaging platforms available through social media or mobile device applications (ref: NARA Bulletin 2015-02: "Guidance on Managing Electronic Messaging").

Senders and recipients of these messages independently determine whether the message and its attachments meet the record definition for their respective office. (FDA's Records Management Guidance for Email Communications).

When preserving email records, per 36 CFR 1236.22, the record must preserve the names of sender and all addressee(s), the date the message was sent, and attachments that are an integral part of the record, captured either as part of the email record, or linked to the email and other related records. If users are

identified only by codes or nicknames, or by the name of a distribution list, the full names must also be retained. Temporary email records may be preserved either in their native format or other electronic format that captures all required elements. Permanent emails scheduled for transfer to NARA must be preserved in a format and on a medium that conforms to NARA's transfer requirements or be able to be converted to the required format and medium at the time of transfer.

FDA Capstone Implementation - FDA has adopted a Capstone approach as defined in NARA Bulletin 2013-02: "Guidance on a New Approach to Managing Email Records," and GRS 6.1, "Email Managed Under a Capstone Approach," for automatically capturing and archiving all FDA emails to support their records management and litigation requirements. NARA has defined specific categories of top-level government officials who by virtue of their work, office, or position, are likely to create or receive permanently valuable federal records. FDA's Capstone positions, as approved by NARA, include the FDA Commissioner; Principal Deputy Commissioner and Deputy Commissioners; Associate Commissioners; staff and special assistants to these positions; principal management positions, including Chief Operating Officer (COO), Chief Financial Officer (CFO), Chief Information Officer (CIO), Chief Technology Officer (CTO), Center Directors and Directors of significant program offices; principal advisory positions, including Chief Counsel, Chief of Staff (OC), Chief Scientist; and additional roles and positions that predominantly create permanent records related to mission critical functions or policy decisions and/or are of historical significance that are not addressed in other categories, such as the Deputy COO. See (NARA Form NA-1005, GRS. 6.1-0088-2017-0001).

The email accounts (including email messages and attachments, calendar appointments, and tasks) of the individuals holding Capstone positions are automatically archived and placed on a permanent hold within the email system to ensure that they remain accessible for discovery or FOIA requests and are preserved as permanent records. The remainder of FDA email accounts (non-Capstone officials) are temporary, and are archived and retained for 7 years, after which they are deleted, unless subject to a hold.

The Capstone approach does not replace FDA personnel responsibilities for managing their email records to support their Center/Office's ongoing business needs and comply with FDA recordkeeping requirements. Furthermore, the FDA Email system (Outlook) is not acceptable for maintaining the official record copy of important program-related emails. Emails and electronic messages that are related to or support FDA administrative or program records must be captured and filed with the related records or case files in the relevant official recordkeeping system for the required retention period. This requirement is mandatory when the retention period for the program records is longer than the default 7-year archive period implemented for non-senior official accounts under Capstone.

Transitory emails - FDA personnel may delete transitory emails, which are emails needed only for a short time (generally less than 180 days) and that are not required to meet legal or fiscal obligations, or to initiate, sustain, evaluate, or provide evidence of decision-making, when no longer needed, in accordance with RCS series FDA-9480b (GRS 5.2, item 010). Nonrecord emails, not containing any information documenting FDA actions or activities, may also be deleted.

Use of Non-Official Electronic Messaging Accounts - FDA personnel are prohibited from using personal or non-official email accounts and devices to conduct official FDA business. The use of non-official accounts is only permitted in extentuating circumstances (i.e., email interruption, computer issues, etc.). During such instances, if email and electronic messages are created that document FDA business and meet the requirements of a federal record, FDA personnel must send a copy of the email to an official account at the time of the original creation or transmission of the record, or forward a copy to an official FDA account, or otherwise capture it in an FDA approved EIS within 20 days of creation or transmission.

D. Social Media

The use of social media as an official FDA channel of communication is overseen jointly by the Office of External Affairs (OEA) Web and Digital Media Staff and OIMT, and is governed by the FDA Social Media Policy (November 2015). FDA social media platforms may include Twitter, Facebook, YouTube, LinkedIn, blogs, podcasts, and others. Only approved platforms can be used for discussing FDA-related matters. Use of personal accounts is prohibited.

The FDA Social Media Policy establishes social media content posted using authorized FDA accounts and platforms as an official means for the Agency to communicate with the public and exchange information in support of FDA's mission, and as such, meets the criteria of an official record. Even when content shared or linked by a post reflects information found on FDA.gov or other official sources within the FDA environment, the action of posting on an FDA social media platform represents an engagement with the public to convey official information. Comments and interactions from the public to FDA social media accounts are not considered to be FDA content and are not part of the record.

To capture a complete record copy of FDA social media posts, the account owner must capture the content of the post, along with the account name, date, and social media platform where posted, and maintain the record within an FDA-owned repository or recordkeeping system. FDA posts residing on the social media platform are not owned by FDA and cannot be considered the official record. For additional guidance on acceptable methods for capturing, managing,

and disposition of social media content as records, see Records Management Guidance for FDA Social Media Content.

E. Web Records

In accordance with FDA's Internet/Intranet management policies, all web content posted on FDA.gov or other agency internet sites is a copy of official program records and therefore is considered nonrecord material. SMG 3215.2, "Archiving and Unpublishing Web Content Policy", states that "information posted on FDA.gov and the FDA's intranet sites constitute information or access copies and should be managed in accordance with programmatic needs, while official records are maintained in an official recordkeeping system in accordance with the retention periods authorized by the National Archives and Records Administration." Documents and other content that are disseminated via FDA websites are records belonging to the program office that created it and they are responsible for maintaining the record.

Centers and Program Offices are responsible for ensuring that the official record of the web content they create for FDA websites is filed in their recordkeeping system and maintained throughout its full lifecycle in accordance with the applicable approved FDA RCS.

FDA website management records include any material and data, including site policies and procedures or design documents (wire frames, site designs, etc.), dealing with the creation, management and maintenance, and use tracking and metrics of an FDA website. These records are retained following the guidance and retention periods described in the approved FDA RCS series: FDA 9911, Information Technology Oversight and Compliance Records; or FDA 9931, Information Technology Operations and Maintenance Records.

F. Managing FDA Records in the Cloud

FDA records management requirements apply to all FDA records created, used, or maintained in the cloud, just as they would if the records were stored on Agency computers. FDA Centers/Offices considering use of cloud computing solutions must ensure that Agency records requirements are adequately addressed. Organizations should include the FDA RO or designee, Center/Office ARLO, and/or other appropriate records management staff, in the planning, development, deployment, and use of cloud computing solutions, to determine what records will be captured, managed, and made available to authorized users, and which appropriate retention periods will be applied. NARA Bulletin 2010-05: "Guidance on Managing Records in Cloud Computing Environments," provides additional records management guidance on the topic of metadata and cloud computing, including a contracting clause to use when procuring cloud computing solutions and negotiating contracts with service providers. This clause can be

modified to fit the planned type of service and the program office's specific records management needs.

7. Roles and Responsibilities

A. HHS Senior Agency Official for Records Management (SAORM)

The HHS Senior Agency Official for Records Management is the Department level senior official at the Assistant Secretary level, or its equivalent, who acts on behalf of all HHS components and operating divisions to ensure that they efficiently and appropriately comply with all applicable records management statutes, regulations, NARA policies, and the requirements of OMB M-19-21, "Transitioning to Electronic Records."

B. The FDA Commissioner and Deputy Commissioner for Operations & Chief Operating Officer

The FDA Commissioner is ultimately responsible for creating and preserving records that adequately and properly document the organization, functions, policies, decisions, procedures, and essential transactions of FDA. The responsibility for establishing a program to ensure compliance with applicable Federal laws and regulations has been delegated to the Deputy Commissioner for Operations & Chief Operating Officer.

C. Director, Office of Enterprise Management Services (OEMS)

The Director of OEMS is responsible for providing the leadership, planning, overall policy, guidance, and general oversight of records management in FDA and will:

- designate, in writing, an FDA Records Officer (FDA RO);
- ensure the FDA RO has adequate skills, training, resources, time, and appropriate authority to execute duties assigned, including current training on email policies and procedures;
- ensure the implementation of a records management program within the Agency to accomplish the objectives identified in federal regulations, in HHS and FDA policies and procedures; and,
- ensure the FDA RO incorporates records management principles and policies in all phases of the EPLC process.

D. The FDA Chief Information Officer (CIO)

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

- incorporate records management requirements and policies into the Agency's overall information resources management (IRM) policy and planning;

- work in conjunction with OEMS to ensure the FDA RO incorporates records management principles and policies in all phases of the EPLC process; and,

- work with the Chief Information Security Officer (CISO), to ensure technical security of FDA electronic records by providing detailed monitoring and enforcement tools and procedures as well as the requirements for reporting established under the SMG 3251.12, “Information System Security and Privacy Policy”.

E. The FDA Records Officer (FDA RO)

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

- serving as the official overseeing the FDA’s Records Management Program and ensuring FDA has up-to-date records management guidelines;

- ensuring Agency senior officials are aware of their programmatic and individual records management responsibilities;

- creating and maintaining a network of ARLOs responsible for overseeing the Records Management program in the various Centers/Offices;

- developing and disseminating instructions and operating procedures, as needed, supplementing the FDA and HHS-wide policy to meet the unique records management requirements of organizations within the FDA;

- coordinating, developing, and updating comprehensive records control schedules for all Agency records regardless of media or format;

- disseminating notices and instructions for litigation holds and other types of legally required holds in accordance with the OCC, HHS Records Officer, and HHS Policy for Litigation Holds guidance;

- serving as the primary official who coordinates FDA’s records management matters with NARA and other oversight agencies, including notifying NARA of

any actual, impending, or threatened unlawful removal, defacing, alteration, corruption, deletion, erasure, or other destruction of records in FDA's custody;

- providing records management training in accordance with this policy to ensure compliance with the Federal Records Act;
- ensuring compliance with records management principles and policies in all phases of the EPLC process;
- providing technical advice and training to all FDA organizations regarding the establishment and maintenance of effective records management programs;
- promulgating and communicating FDA wide policies and guidance that reflect records management missions and goals and incorporate Federal requirements;
- conducting a formal evaluation on two elements of the records management program annually to measure the effectiveness of FDA's Records Management Program and practices;
- conducting annual audits for records management retention compliance;
- coordinating fiscal year (FY) interagency agreement(s) with NARA and Agency budget officials for the storage and servicing of records;
- providing support to the FDA Essential Records program;
- completing training requirements as specified by NARA to obtain the Agency Records Officer Credential within one year of assuming the position, and periodically renewing the credential as required;
- authorizing the transfer of permanent records to NARA; and,
- ensuring that recordkeeping requirements are established, implemented, and periodically updated for all offices at all levels and all record media.

F. Center/Office Directors

Each Center/Office Director will:

- ensure that their Center/Office has an effective and efficient record management program that allows their employees to manage their records in all formats, in accordance with FDA RCS;

- designate in writing, an ARLO accountable to the FDA RO, who is designated to oversee the Center/Office program; and,

- ensure the ARLO has adequate skills, training, resources, time, and appropriate authority to carry out their responsibilities.

G. Center/Office ARLOs

While the Center/Office Directors ultimately hold managerial responsibility for the management of records within their Center/Office, the Center/Office ARLOs hold the following functional responsibilities, some of which are shared between the Center/Office Director and the ARLO, as appropriate, within each Center/Office.

ARLOs must implement a records management program within their Center/Office to support and accomplish the objectives identified in Federal regulations and HHS/FDA policies and procedures. Minimum program components include responsibility for:

- identifying recordkeeping requirements for all programmatic and administrative records, regardless of physical form or characteristic, including information created, communicated, or stored in digital or electronic form;

- evaluating the value of records within their Center/Office areas of responsibility, to serve as a basis for assigning records retention and disposition instructions, and implementing the most responsive and cost-effective means for managing them;

- developing and maintaining file plans, taxonomies and indexing approaches, where appropriate, to simplify the use of, access to, and integration of information within the organization;

- drafting and updating FDA RCS, for records created and maintained, that are specific to their Center/Office's organizational program/mission and are not covered by the Agency-wide schedules or another Center/Office schedule;

- implementing approved RCS to ensure that records are not destroyed without proper authorization;

- reviewing file plans and procedures on a regular basis, or as directed by the FDA Records Management Program, to ensure they are current and updating them as necessary;

- assisting in planning and implementing information technology and reviewing the purchase of records management equipment and services to ensure they conform to Federal and Agency statutory and regulatory requirements;

- providing records management briefings for all managers and training to staff within their organizations, as needed;

- developing records management oversight roles and communication networks with all program units, including field offices and other facilities, as appropriate, to ensure that the records management program is implemented at all sites under their jurisdiction;

- developing and disseminating instructions and operating procedures, as needed to supplement Agency-wide policy, to meet the unique records management needs of their organizations, and to support a records management program within the organization;

- ensuring records and other types of required documentary materials are not unlawfully removed from FDA by current or departing officials, employees, or contractors;

- performing an annual review to determine changes in any programs that would create a change in the RCS and taking the appropriate action;

- ensuring funds availability for records storage and reference services;

- incorporating language into all contracts, for services, systems development, or goods; and clear guidelines for the lifecycle management, protection, and ownership of FDA records and information developed or used by the contractors; and

- providing support to an essential records program.

While emergency operation records should be identified and managed in the Continuity of Operations Plan (COOP), ARLOs need to work with the FDA COOP coordinators and FDA Essential Records Officer to ensure all of the records are identified and protected. The location and access permissions for the legal and financial rights records are to be included in the COOP.

H. Center/Office/Program Records Custodians, Coordinators or Designees

Where a Center/Office or major program creates specific records management related roles to support and represent their records management strategy and operations, these custodians, coordinators or designees should communicate regularly with the Center/Office ARLO, in order that appropriate information on records management needs and requirements is exchanged.

I. FDA Office of Chief Counsel (OCC)

The FDA OCC assists in determining what records are needed to provide adequate and proper documentation of FDA activities and in specifying appropriate disposition for FDA records.

The OCC will also review policies and procedures related to records and information management that have Agency-wide application or impact, review and approve additions and changes to FDA RCS, and assist with related issues.

OCC provides instructions for implementing litigation holds required to comply with legal requirements.

J. FDA Managers and Supervisors

All FDA managers and supervisors are responsible for ensuring that:

- FDA personnel under their area of responsibility are aware of and adhere to FDA and HHS records management policies and procedures, and that they complete required initial and annual records management training;

- departing employee’s record materials, including email records, have been reviewed, filed, or collected, as appropriate, prior to the employee’s departure; and

- departing employees comply with policies and procedures regarding preservation, transfer and deletion of records.

K. All FDA personnel are responsible for:

- creating and managing the records necessary to document the Agency's official activities and carrying out their assigned duties in accordance with FDA recordkeeping requirements;

- protecting FDA records and information containing national security information, Controlled Unclassified information (CUI), PII, PHI, and other

proprietary or sensitive information in accordance with applicable FDA and other federal information security and privacy requirements;

- destroying records only in accordance with approved RCS and FDA policies, and never removing records from FDA without authorization;

- completing required annual records management training;

- maintaining records in a safe storage environment that promotes efficient retrieval, in accordance with established filing procedures and plans, and maintaining personal papers and nonrecord materials separately from FDA records;

- completing the Employee Departure Process before separation from FDA; and,

- reporting incidents immediately to their supervisors, of records that are inadvertenly removed, altered, lost, or destroyed.

L. FDA Contractors

In addition to the responsibilities applicable to all FDA personnel listed above, FDA contractors are responsible for:

- notifying the appropriate Contracting Officer or FDA Records Management staff about any inadvertent or unauthorized disclosures of FDA information, data, documentary materials, records and/or equipment;

- ensuring that appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of FDA information, data, documentary materials, records and/or equipment;

- returning information, data, documentary materials, and records back to FDA control when no longer needed, or as otherwise directed; and,

- working with their project manager to ensure that records are being filed in the program office's official recordkeeping system.

8. Technical Assistance

Questions on records management should be addressed to the ARLO in each Center/Office or to the FDA RO or designee.

Any violation of the legal and/or regulatory limits on the removal of records and information by FDA employees or individuals conducting business on behalf of FDA under agreements, who are separating from the Agency, should be forwarded to the Office of Ethics and Integrity, Office of Operations, and the ARLO in each Center/Office.

9. Glossary

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

10. Effective Date

This guide is effective on September 2, 2022. It supersedes the SMG titled: SMG 3291.1, “Records Management Policy” issued on November, 2008.

11. Document History - SMG 3291.1, “Records Management Policy”

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	11/2008	N/A	Office of Information Management	FDA Chief Information Officer
Revision	09/01/2022	N/A	Office of Enterprise Management Services (OEMS)	Tiffany Branch, Director, OEMS

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