SMG 3291.12

FDA Staff Manual Guides Volume III – General Administration

Information Resources Management – Records Management

FDA Records Destruction Policy

Effective Date: 09/29/2025

1. Purpose

The purpose of this Records Destruction Policy Staff Manual Guide (SMG) is to establish responsibilities and requirements for the legal and authorized destruction of Food and Drug Administration (FDA) temporary federal records. The prompt and legal disposal of these records, when eligible, promotes efficient management of FDA records; reduces risk; saves money and resources; and saves staff time when responding to formal information requests and other business needs.

This SMG outlines the overall FDA policy and requirements for approval and destruction of federal records that have met their retention requirements and are no longer needed for business. Specific procedures for determining disposal eligibility and carrying out destruction of different types of federal records are described in more detail in the FDA Temporary Records Destruction Standard Operating Procedure (SOP). Centers/Offices may follow the recommended procedures identified in the FDA-wide Destruction SOP, or they may choose to adopt their own procedures to meet their unique program requirements if they comply with this SMG. This SMG covers records destruction at FDA Headquarters, field offices, and other approved remote work locations.

This SMG also briefly describes how FDA nonrecord materials must be destroyed, if nonrecord materials are identified by FDA Centers/Offices, or by FDA personnel, as part of the process of identifying temporary federal records eligible for destruction.

2. Background

The Federal Records Act of 1950, as amended, established the National Archives and Records Administration (NARA) to maintain and approve the Government's records and established that all Federal records are to be kept indefinitely unless they are of a temporary nature and their destruction is approved by NARA by way of NARA-approved Records Control Schedules (RCS). Agencies must submit RCS to NARA to request disposition authority for their respective records. Once approved, RCS designate agency federal records as either permanent or temporary. Given their long-term historical value, permanent federal records are timely transferred or accessioned to NARA. Agencies are authorized to destroy temporary federal records when they have reached the end of their schedule retention period, as established by the applicable RCS.

3. Policy

Destruction of Temporary Records

FDA's SMG 3291.1, Records Management Policy, establishes that Centers/Offices must dispose of temporary records that have reached the end of their approved retention period as defined by the relevant FDA RCS, and the records are no longer needed for Agency business. The destruction of FDA records must be carried out according to the following requirements:

- FDA records disposal activities must be conducted in a manner that ensures protection of FDA information contained in the records, including Personally Identifiable Information (PII), Protected Health Information (PHI), proprietary information, and other sensitive information, and that safeguards FDA interests and the safety, security and privacy of individuals and organizations.

- All eligible temporary records are to be destroyed in accordance with the disposition instructions found in NARA-approved FDA RCS.

Center/Office ARLOs or designees must ensure that records proposed for destruction are not subject to any active legal hold(s), or any pending requests under the Freedom of Information Act (FOIA). This should include consulting the FDA's legal hold platform, as well as the FOIA personnel assigned to their Center/Office.

- FDA personnel must carry out destruction or deletion of FDA temporary records following established procedures and with the approval, as needed, of their Center/Office Assistant Records Liaison Officer (ARLO).

    - ARLO approval is not needed for FDA personnel to destroy transitory federal records of short-term value, and/or intermediary federal records that are created or used in the process of creating subsequent federal record(s). To

qualify as transitory and/or intermediary records, such records cannot be required to meet legal or fiscal obligations, or to initiate, sustain, evaluate, or provide evidence of agency decision-making.

  - For further information on transitory and/or intermediary federal records, see FDA Temporary Records Destruction SOP.

- FDA personnel carrying out the destruction or deletion of other eligible temporary federal records must proceed in coordination with business process owners, managers of the program offices, and other stakeholders as applicable. Center/Office ARLOs may establish their own records destruction procedures and guidance that are consistent with this policy. Alternatively, Centers/Offices may follow the agency-wide procedures that are outlined in the FDA Temporary Records Destruction SOP.

- As noted above, FDA personnel may destroy transitory records, as well as eligible intermediary records, without ARLO approval. For destruction or deletion of all other types of temporary federal records, destruction procedures must include a process for documenting specifically what records are being destroyed. Documentation must include a description of the records being destroyed, the corresponding FDA file code and records series title, the NARA-approved disposition authority, records volume and dates, names of approving records owner and manager as appropriate, and the Center/Office ARLO's approval.

- FDA Form 4081, Approval Request to Destroy FDA Records, may be used for this purpose, but Center/Office ARLOs may adopt their own format for maintaining a log of destroyed records.

- Authorized destruction of FDA temporary records, whether in FDA office space at headquarters, field offices, or overseas offices, Center/Office document rooms, at NARA FRCs, commercial records storage facilities, or approved remote worksites, must be carried out using appropriate methods that reduce the risk of information disclosure and that meet applicable destruction requirements of 36 CFR 1226.24 6.24, How must agencies destroy temporary records?

  - All FDA physical records are to be treated as sensitive and must be shredded. FDA personnel must NOT place FDA-related paper documents in non-secure office or off-site recycle bins or trash receptacles.

  - FDA personnel must use a cross-cut shredder for disposal of temporary records accumulated in FDA offices, or while teleworking or working remotely.

- Office of Facilities Engineering and Mission Support Services (OFEMS) contracts for records destruction/shredding services at FDA Headquarters White Oak Campus and other designated authorized locations in the Washington, DC metro area. FDA personnel should use the locked shred bins available throughout shared

office space to dispose of physical records, including CDs and DVDs, or make special arrangements for destruction of larger volumes of materials. See the Destruction SOP for details on acceptable items/media and how to utilize contracted shred services.

- FDA field office managers (domestic and foreign) must ensure that destruction/shredding services are available that are consistent with this policy. Foreign offices may ship records back to the U.S. or destroy records onsite.

- NARA Federal Records Centers (FRCs) carry out destruction of FDA records stored at the FRCs. Upon notification from NARA that FDA records are eligible for destruction, the FDA Records Officer (RO) or designee will coordinate with the respective Center/Office ARLOs and records owners to obtain approval for destruction. The RO or designee will submit the destruction approval to NARA or provide justification for extended retention. (See the Destruction SOP for more details on the NARA FRC approval process.)

- Commercial records storage facilities carry out destruction of FDA records in coordination with and approval from respective Center/Office ARLOs, following procedures mutually agreed upon by FDA and the storage provider as established in contractual agreements. Commercial storage facilities must meet NARA standards and requirements outlined in 36 CFR 1234, Facility Standards for Records Storage Facilities.

- Witnessed shredding of FDA records is optional. Center/Office ARLOs may determine if a witness is required due to the sensitivity or classification of the information being destroyed (e.g., privacy; proprietary; security concerns).

- Personnel must notify their Center/Office ARLO and the FDA RO or designee immediately if they become aware of any unlawful or accidental destruction, deletion, alteration, or removal of FDA records from Federal custody. Based on the level of the incident, the FDA RO or designee will report the incident to NARA, as identified in 36 CFR 1230.14, How Do Agencies Report Incidents?

Destruction of Nonrecord Documents and Information

As part of the process of identifying temporary federal records eligible for destruction, FDA Centers/Offices, and/or FDA personnel, also may identify nonrecord materials in FDA workspaces or on FDA computers or other media.

Nonrecord materials are US Government-owned documents and/or information that are excluded from the definition of a federal record. Such nonrecord materials either fail to meet the general statutory criteria for record status (44 USC 3301(a)(1)(A)) or fall under one of listed exceptions to that definition (44 USC 3301(a)(1)(B)). Notably, the legal definition of a federal record specifically excludes the following:

- library and museum material made or acquired and preserved solely for reference or exhibition purposes;

- duplicate copies of records preserved only for convenience.

No prior approval is needed, and no documentation is required, for FDA Center/Offices, and/or FDA personnel, to destroy or delete nonrecord materials, including electronic copies of such nonrecord materials. It is important to remember, however, that multiple copies of the same document may each have record status depending on how they are used by the Center/Office, and/or FDA personnel, in conducting agency business. (36 CFR 1222.12 What types of documentary materials are Federal records?).

Any destruction of nonrecord materials must be conducted in a manner that ensures protection of FDA information contained in the materials, including Personally Identifiable Information (PII), Protected Health Information (PHI), proprietary information, and other sensitive information, and that safeguards FDA interests and the safety, security and privacy of individuals and organizations.

- FDA nonrecord materials are to be treated as sensitive and must be shredded. FDA personnel must NOT place FDA-related paper documents in non-secure office or off-site recycle bins or trash receptacles. FDA personnel must use a cross-cut shredder for disposal of nonrecord materials accumulated in FDA offices, or while teleworking or working remotely.

FDA nonrecord materials are distinguishable from personal papers belonging to individual FDA employees. Personal papers belong to the individual, i.e. they are not US Government-owned documents and/or information, and they are not used to conduct agency business. Personal papers are used exclusively for that individual's benefit and may include such items as diaries, calendars, or materials accumulated by an individual before joining the Government. The relevant individual makes any and all decisions with respect to the destruction of personal papers.

Destruction of Electronic Records

FDA personnel must obtain approval from their ARLO prior to deleting official electronic records eligible for disposal from Center/Office electronic recordkeeping systems, shared drives, OneDrive, or other electronic records storage locations. However, without prior approval, personnel may delete, their electronic transitory federal records, and/or their electronic intermediary records.

- Electronic records stored in electronic recordkeeping systems in which disposition schedules have been configured into a system file plan will not be destroyed

automatically without ARLO and applicable stakeholder approvals. Programmed disposition processing will not be executed without prior approval.

- FDA original source records (physical or electronic) used to create a digital version that serves as the official record copy can be destroyed after all applicable quality control (QC) and validation requirements have been met, and the final digital records have been saved in an approved FDA recordkeeping system or other approved records repository. See SMG 3291.10, FDA Temporary Records Digitization Policy for complete digitization standards and requirements. See also FDA-9137, Source Records (GRS 4.5, item 010) for the applicable disposition authority.

- The Office of Digital Transformation (ODT) will perform destruction of electronic records stored on FDA systems and servers, hard drives, laptops, and other computer-related media used to store FDA records. Effective electronic media destruction or sanitization methods must be applied to electronic media to ensure that records and other sensitive information are not recoverable, in accordance with FDA SMG 3251.12, Information Security and Privacy Protection Policy, Appendix S - Sanitization of Computer-Related Storage Media. Destruction or deletion of records stored on media must be approved by the Center/Office ARLO.

Exceptions to Records Retention Policies

- As noted earlier in this SMG, Center/Office ARLOs or designees must ensure that records proposed for destruction are not subject to any active legal hold(s), or any pending requests under the Freedom of Information Act (FOIA). This should include consulting the FDA's legal hold platform, as well as the FOIA personnel assigned to their Center/Office. If any such hold(s) or pending FOIA requests are identified, destruction of potentially relevant records is automatically suspended. In such cases, paper and electronic records destruction must cease immediately and cannot resume until the Center/Office ARLOs or designees receive appropriate guidance to that effect.

As circumstances may warrant, and in consultation with business process owners, managers of the program office, and other stakeholders as applicable, FDA personnel may also suspend the destruction or deletion of eligible temporary federal records until further guidance is received.

- Emergency destruction of FDA records is authorized when records could pose a menace to human health or life and to property, with prior NARA approval. Similarly, when records outside the territorial limits of the continental United States are subject to a war or other hostile action, the HHS Secretary or FDA Commissioner may authorize the destruction of such records; see 44 U.S.C. 33, Disposal of Records for reporting requirements.

4. Authorities and References

- Federal Records Act of 1950, as amended (FRA), (44 U.S.C. Chapters 21, 29, 31, and 33)
- FDA SMG 3291.1: Records Management Policy (Effective Date: 09/02/2022)
- 36 CFR Chapter XII, Subchapter B, Parts 1220-1239, "Records Management"
- SMG 3291.10, "FDA Temporary Records Digitization Policy" (Effective date: 04/06/2022)
- FDA SMG 3251.12: Information Security and Privacy Protection Policy, Appendix S – Sanitization of Computer-Related Storage Media (Effective date: 03/15/2023, Changed: 04/04/2023).
- 44 U.S.C 3106: Unlawful Removal, Destruction of Records
- 44 U.S.C. Chapter 33: Disposal of Records
- Office of Management and Budget (OMB), Circular A-130, Managing Information as a Strategic Resource (Effective Date: July 27, 2016)

5. Roles and Responsibilities

FDA Records Officer (FDA RO) or Designee

- Establishes policies and procedures to accomplish the effective and legal disposition of eligible temporary records in accordance with 36 CFR Part 1224, Records Disposition Programs.
- Coordinates, develops, and updates comprehensive records disposition schedules for all FDA records, regardless of media or format, which provide authorized retention and disposition instructions.
- Ensures that commercial records storage facilities used to store FDA records meet NARA standards and requirements set forth in 36 CFR Part 1234, Facility Standards for Records Storage Facilities, and submits required documentation in accordance with 36 CFR 1234.30.
- Coordinates records holds actions with NARA for records stored in FRCs, as needed.
- Coordinates with ARLOs to approve destruction of records stored at NARA FRCs at the end of their retention period.

- Reports cases of unauthorized disposition of FDA records, including their unlawful or accidental destruction, deletion, alteration, or removal from Federal custody, to NARA (see 36 CFR 1230.14 How do agencies report incidents?).

FDA Chief Information Officer (CIO) or Designee

- Provides oversight and approval in the planning, design and operation of FDA information systems to incorporate records retention and disposition requirements, in accordance with OMB Circular A-130, Section 5 (h), Policy - Records Management.

- Collaborates with the FDA RO or designee to provide guidance for information systems design and operations that adheres to records management retention and disposition policies.

- Establishes policies and procedures that preclude records from being deleted from FDA information systems except as authorized by FDA RCS.

- Establishes procedures for effective media sanitization methods to prevent unauthorized access, use and/or disclosure of information.

Office of the Chief Counsel (OCC)

- Provides legal advice and assists in determining the retention period of Agency records that are needed for legal purposes.

- Provides legal advice regarding and assistance with respect to the FDA legal hold platform.

Facilities Management

- Contracts records destruction/shredding services for use by FDA Headquarters Centers/Offices located within the Washington, DC metro area. Onsite services include delivery and pickup of lockable shred containers; special pickup of boxed paper records and materials; and secure destruction.

- The Contracting Officer's Representative (COR) for the shred services contractor, with ARLO approval, may honor special requests for local shredding services at offsite locations within the Headquarters region. As determined by the Center/Office ARLO, it is optional to have a qualified FDA employee to serve as a destruction witness for both onsite and offsite destruction.

- FDA facilities outside the DC area must ensure that destruction/shredding services are available and consistent with this policy.

- Notifies OMES/ODIGA/DIG/RMB of any records found in FDA buildings that may be subject to damage or inadvertent destruction in such locations.

Assistant Records Liaison Officer (ARLO)

- Approves processes and procedures for destruction of temporary federal records in accordance with the approved FDA RCS and Center/Office work processes.

- Implements the disposition instructions found in FDA RCS and/or NARA General Records Schedule (GRS) and determines destruction eligibility of temporary records materials.

- Ensures that records proposed for destruction are not subject to any active legal hold(s), or any pending requests under the Freedom of Information Act (FOIA). This should include consulting the FDA's legal hold platform, as well as the FOIA personnel assigned to their Center/Office. Notifies RMT when records stored at FRCs are to be placed on hold.

- As required, maintains a log or list of all destroyed or deleted records, and in coordination with the Records Owners/Custodians, preserves this information together with documentation of the respective records and other artifacts (i.e., Certificate of Destruction or NARA equivalent), as applicable. Provides copies of the log or list of records destroyed or deleted to the RO or designee as needed to respond to discovery or other information requests.

- Coordinates with the records owners and reviews all documentation provided by OMES/ODIGA/DIG/RMB regarding destruction of eligible physical records stored at an FRC (i.e., NA-13001's (or electronic equivalent), records lists and/or spreadsheets), to determine if the records identified should be destroyed, have disposition date extended, or be permanently withdrawn from FRC. Communicates decision to the FDA RO or OMES/ODIGA/DIG/RMB, who submits response to NARA.

Records Owners/Custodians and all FDA Personnel

- Determine when records in their custody or within their area of responsibility are eligible for destruction in accordance with disposition instructions listed in NARA-approved records disposition schedules.

- Prior to destruction, consult internally with the ARLO and/or records managers as appropriate to ensure there are no restrictions on the destruction of the applicable records.

- Coordinate with ARLO to maintain copies of logs identifying destroyed or deleted records. FDA Form 4081 may be used for this purpose.

- Safeguard FDA records from unauthorized disclosure while in their custody, and throughout the destruction process.

Contractors Performing Shredding/Destruction

- Must provide secure, convenient, cost-effective, and environmentally friendly methods to dispose of FDA sensitive documents and other materials.

- Must safeguard FDA information from unauthorized disclosure during pickup, transportation, and destruction. Shredding/destruction contracts must specify requirements for secure transportation and acceptable method of destruction.

- Must issue a signed "Certificate of Destruction" when shredding activity is completed.

6. Effective Date

The effective date of this guide is 09/29/2025.

7. Document History: SMG 3291.12 "FDA Records Destruction Policy"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	09/16/2025	N/A	Office of Management and Enterprise Services (OMES)	Director, OMES