SMG 3291.3

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Records Management

Records Management Guidance for New and Departing FDA Personnel

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1. Purpose

The purpose of this Staff Manual Guide (SMG) is to establish records management (RM) policies and responsibilities for new and departing Food and Drug Administration (FDA) personnel. “FDA personnel” as used in this SMG, applies inclusively to all civilian government employees, Commissioned Corps personnel, contractors, local or foreign government exchange program participants, guest researchers, visiting scientists, fellows, interns, volunteers, or any other non-government employees. This SMG defines requirements for orientation and training of new FDA personnel covering their recordkeeping responsibilities, as well as recurring training throughout their tenure at the Agency, such as the Agency’s Annual Records Management Training. The SMG also outlines exit procedures that departing personnel and their supervisors must take relative to the departing personnel’s Agency records so that the records remain in FDA custody and are available and usable throughout the applicable records retention period, after the departure of the relevant personnel.

A separate SMG covers similar responsibilities and requirements for FDA Senior Officials (see SMG 3291.3a Records Management Guidance for New and Departing Senior Officials).

2. Background

FDA personnel create, receive, and maintain Federal records as part of their work responsibilities. Official FDA records contain information relating to foods, drugs, other regulated materials, and long-range issues of Agency-wide significance, as

well as administrative and operational information, that must be remain in FDA custody, even after the original records owner departs the Agency. In addition to Federal records, FDA personnel also may create and accumulate personal papers and nonrecord materials while in the work place.

The National Archives and Records Administration (NARA), Department of Health and Human Services (HHS), and FDA have issued regulations, policies, and guidelines regarding the management of official records, nonrecord materials, and personal papers. This SMG supplements the overarching policy and requirements for managing FDA records that are outlined in SMG 3291.1, FDA Records Management Policy, and focuses on the records management requirements related specifically to the onboarding and departure processes for all FDA non-Senior personnel.

3. Authorities & References

This SMG is derived from the Federal Records Act of 1950 (44 U.S. Code, Chapters 29, 31 and 33), as amended. It is aligned with the regulations issued by NARA in 36 CFR, Chapter XII, Subchapter B. Penalties for the unlawful removal or destruction of Federal records are documented in Title 18 U.S.C. 641 and 2071.

Additional references relevant to this SMG include:

- HHS-OCIO-PIM-2020-06-004, HHS Policy for Records Management
- Inside.FDA - eArrive: New Employee Onboarding System
- Inside.FDA - eDepart: FDA Employee Exit System
- FDA Office of Talent Solutions (OTS) Standard Operating Procedures - FDA OTS SOP 700-04 Processing Separations revised June 2019 (Final).pdf
- FDA SMG 3291.1, FDA Records Management Policy, September 2022

4. Definitions

This SMG addresses Federal records, nonrecord materials, and personal papers, that are in the custody of FDA personnel. The definitions of these key RM terms can be found in the FDA Records Management Master Glossary.

5. Policy

This SMG applies to all FDA personnel who have access to FDA supported facilities or FDA information, systems, or resources. As noted earlier, “FDA personnel” applies inclusively to all civilian government employees, Commissioned Corps personnel, contractors, local or foreign government exchange program participants, guest researchers, visiting scientists, fellows, interns, volunteers, or any other non-government employees.

The Federal Records Act, NARA's Code of Federal Regulations, and other statutes, require all Federal agencies and personnel to create records that document their activities, file records for safe storage and efficient retrieval, and dispose of records according to Records Control Schedules (RCS) approved by NARA. It is the responsibility of all FDA personnel to document what they do and to protect Federal records in their custody, in order to efficiently perform their work.

Staff Manual Guide (SMG) 3291.1, "FDA Records Management Policy," describes and identifies details regarding the principles, standards, responsibilities, and requirements for managing FDA records, regardless of format, in compliance with applicable Federal laws, regulations, policies, and guidance. It provides the framework for RM program guidance and operating procedures for lifecycle records management, covering records creation or receipt, maintenance and use, and proper records disposition. This SMG outlines supplemental RM policies and procedures specific to the onboarding and departure process for FDA personnel that are consistent with NARA's guidance as described in Documenting Your Public Service.

A. Incoming FDA Personnel

A critical part of the FDA onboarding process is records management (RM) orientation and training for new FDA personnel, as required by 36 CFR 1220.34(f) and 36 CFR 1222.24(b), that helps prepare them to carry out their RM responsibilities.

- A Records Management briefing is presented at both the FDA 'New Employee Orientation (NEO)' and the 'Non-Employee (Scientist) Orientation (NESO)'. These briefings provide new employees and non-employees with an overview of FDA's RM requirements.

- Also, all new FDA personnel must complete the current version of the Annual FDA Records Management Training. The training must be completed within 30 days of receiving an email notification providing information to access the current training available on the FDA training system. While contractors do not attend orientation briefings, they must complete the initial RM training requirement.

FDA personnel must also renew their RM training annually as a refresher of their records management responsibilities. Once a year, e-mail notifications are sent to all FDA personnel asking them to complete the latest version of the mandatory Annual Records Management Training. The email notification provides specific dates and other information related to the training. Upon receipt of the email notification, all FDA personnel must complete the training within the specified timeframe. Failure to complete the training by the deadline will result in loss of their FDA network access, until they complete the training. The current version of

the Annual Records Management training presentation is also available on the FDA Records Management Hub Training page throughout the year for reference.

Additionally, FDA Centers/Offices may require RM training specific to their Center/Office, provided through the Assistant Records Liaison Officer (ARLO) and/or other designated staff. NARA also provides a variety of optional RM training to supplement FDA's training.

B. Departing FDA Personnel.

The FDA Office of Talent Solutions (OTS) provides comprehensive procedures for processing separations. (See SOP 700-04, "Processing Separations and eDepart," or successor SOP.) All FDA personnel are required to follow this SOP during the departure process. It applies to personnel leaving the FDA, including those transferring to another HHS Operating Division (OPDIV) or other Federal agency outside HHS. It also applies to contractors and affiliates moving from one office/division, contract, or task order to another. Guidance and procedures outlined in this SMG are specific to records management requirements.

Departing FDA personnel will observe the following guidelines as required by HHS and FDA policies. They must first determine, in consultation with their FDA supervisor, whether they are a custodian of records or other information that are subject to a litigation hold. If yes, they must comply with the directions in the relevant litigation hold, and/or any specific instructions issued by FDA's Office of Chief Counsel to ensure the records are preserved. Otherwise, departing personnel will follow the steps below:

1. Departing personnel must identify and separate all Federal records from nonrecord materials and personal papers. Departing FDA personnel **must not destroy or remove Federal records** from the Agency, and they should ensure that their official records, whether in physical or electronic form, are available to their successor and/or can be retained by FDA for their full retention period as defined by applicable RCS.

2. For records eligible for disposition in accordance with the authorized RCS that are not subject to any litigation hold, departing personnel must contact the appropriate Center/Office ARLO, for proper disposition procedures.

   Also, departing personnel should dispose of nonrecord materials, such as duplicate copies of records preserved only for convenience, and reference materials that are no longer needed by their Center/Office for reference or other continuing use, and are not subject to a litigation hold.

3. Generally, departing FDA personnel may take personal papers with them. Personal papers, whether in physical or electronic form, must be clearly designated as such and kept separate from the Agency's official records.

Personnel should consult with the Center/Office ARLO to help determine whether files are considered personal or FDA records. There may be situations in which personal and official files have been intermingled. Those files need to be reviewed and the removal of personal materials approved by the Center/Office Director or designee, to ensure that record management requirements are properly followed. In cases where information about personal matters and FDA business appear in the same document, the document should be copied. The personal information should be deleted or redacted, and the copy treated as the official record. Non-public FDA information must be redacted from the personal copy, if being retained by FDA personnel.

4. As required by FDA SMG 3291.1, "FDA Records Management Policy," FDA electronic records should always be maintained on the FDA network, in an FDA-approved electronic electronic recordkeeping system, or other approved electronic information system or repository, so that they are accessible to authorized FDA staff, when needed. Electronic records owned by departing employees that are not accessible to other FDA staff, including electronic mail (e-mail)/messaging accounts and personal network drives, must be reviewed by the employee and/or supervisor, and with assistance from ODT/OIMT if necessary, transferred or have access reassigned to the supervisor or departing employee's successor, as applicable, so the records remain accessible for their required retention period.

5. Departing personnel must identify and transfer FDA electronic records that reside outside of the FDA network, such as on an FDA laptop local drive, on other electronic media, such as an approved FDA USB drive (e.g., Iron Key), or on personal devices such as a phone, tablet, or personal laptop, to an FDA-approved electronic recordkeeping system, and/or turn them over to their supervisor.

6. Before leaving FDA, departing personnel must obtain clearance from their supervisor and Center/Office ARLOs for records-related items, following Agency procedures. FDA personnel should not have the expectation of taking copies of records or notes on work related documents with them because they are likely to contain non-public FDA information. The clearance process may involve a checklist or automated process, such as eDepart or successor systems, which provides a chain of custody that certifies the departing personnel have returned all physical records in their custody and uploaded or transferred access of electronic records, including email, to their successor(s) or supervisor.

Departing contractors will turn over FDA records, nonrecord copies, and other materials to the Contracting Officer (CO) or Contracting Officer Representative (COR), upon termination of contracts or departure of individual contract employees.

6. Responsibilities

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

- Approves, disseminates and implements Agency-wide policies for new and departing personnel, concerning their record management responsibilities, including electronic records.

B. FDA Records Officer (FDA RO).

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

- develops guidance on RM issues for new and departing FDA personnel, and evaluates compliance with Federal and HHS/FDA laws and guidelines;

- provides RM orientation training for new FDA personnel; and

- works with Center/Office supervisory staff and ARLOs as needed regarding departing personnel to ensure official records are accounted for.

C. Assistant Records Liaison Officers (ARLOs).

- Center/Office ARLOs provide supplemental orientation/training for new FDA personnel specific to Center/Office RM responsibilities, as required by their Centers/Offices, and monitor and work with new personnel to ensure required RM procedures are followed. ARLOs may also recommend other training applicable to RM-related responsibilities.

- Working with the supervisor of departing FDA personnel, ARLOs ensure departing personnel return any records that were created or borrowed from any Document Room. They also provide guidance to assist personnel on how to move records from laptop/computer hard drives, personal network drives, e-mail folders, SharePoint sites, or other applications, databases, or systems not accessible to the supervisor, manager or Contract Officer Representative to a designated office recordkeeping or filing system (physical or electronic), where they will be maintained in accordance with applicable Records Control Schedules.

- ARLOs ensure departing personnel, and their supervisors, appropriately transfer and disposition eligible records prior to departure.

D. Supervisors/Managers.

- Work with the ARLOs to provide guidance and instructions to new personnel on how to manage official FDA records in the performance of their duties.

- Ensure that departing personnel turn over official Agency records, including records maintained in a home office or on the personnel's personal computing devices such as mobile phones and devices, hard drives, removable storage devices, or on other media, and work with ODT/OIMT to identify and reassign electronic records maintained by departing personnel. They ensure that records are moved from laptop/computer hard drives, personal network drives, e-mail folders, SharePoint sites, or other applications, databases, or systems not accessible to the supervisor, manager or Contract Officer Representative to a designated office recordkeeping or filing system (physical or electronic) where they will be maintained in accordance with applicable Records Control Schedules.

- Ensure that a chain of custody process is followed for records, as part of the exit process.

- The supervisor must coordinate with the FDA personnel and the appropriate ARLO or designee to complete the following actions as appropriate:

    - transfer any active work-in-progress information and knowledge to the agreed-upon repository or individual;

    - transfer inactive records to the office recordkeeping system;

    - dispose of convenience copies and other nonrecords; and

    - coordinate with the ARLO or designee on the disposition actions needed for records, including e-mails, held past their retention and now eligible for disposition under the relevant RCS.

E. Records Coordinators (RC).

- Advise onboarding and departing/transferring personnel and their supervisors in the handling and transfer of records.

F. Contracting Officers (and similarly responsible parties overseeing contractors and other non-FDA employees).

- Contracting Officers ensure new FDA contract employees or affiliates adhere to records management requirements, including participation and completion of the mandatory Annual Records Management Training.

- They also ensure that departing contractors turn over official Agency records maintained in a home office or on their personal or other organization's computing devices such as mobile phones and devices, hard drives, CD-ROMs, or on other media, by working with the Contracting Officer's

Representative (COR), project manager, project executive, or other appropriate parties.

G. All FDA Personnel.

- All FDA personnel onboarding with the agency are responsible for completing the required Annual FDA Records Management Training within 30 days of receiving email notification to take the RM training, and every year thereafter, within the specified timeframe.

- Prior to departure from FDA, all personnel must ensure that their records are moved from laptop/computer hard drives, personal network drives, e-mail folders, SharePoint sites, or other applications, databases, or systems not accessible to the supervisor, manager or Contract Officer Representative to a designated office recordkeeping or filing system (physical or electronic) where they will be maintained in accordance with records retention and disposition instructions (refer to applicable Records Control Schedules).

FDA Personnel include, but are not limited to:

- civilian government employees and Commissioned Corps personnel;
- political appointees and contractors;
- local or foreign government exchange program participants;
- guest researchers, visiting scientists, and fellows; and
- interns who have access to FDA supported facilities or FDA information.

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

- 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's 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.

Additional and more comprehensive RM responsibilities are identified in FDA SMG 3291.1, "FDA Records Management Policy," including overall responsibilities for the FDA RO and for all FDA personnel.

7. Technical Assistance

Departing FDA personnel should contact the ARLO or designee in each Center/Office for questions. Any violation of the statutory and regulatory limitations on the removal of documentary materials by FDA personnel who are separating from the Agency should be forwarded to the Office of Ethics and Integrity (OC/OO/OEI), the Director, Office of Enterprise Management Services (OC/OO/OEMS), the FDA RO, and the Center/Office ARLO, as applicable.

8. Effective Date

This SMG is effective on December 21, 2022. It supersedes the SMG titled, "**Records Management Guidance for Departing Employees**," issued on September 23, 2008.

9. Document History - SMG 3291.3, "Records Management Guidance for New and Departing FDA Personnel"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	9/23/2008	N/A	Office of Information Management and Technology (OIMT)	FDA Chief Information Officer (CIO)
Revision	12/19/2022	N/A	Office of Enterprise Management Services (OEMS)	Tiffany Branch, Director, OEMS