SMG 3291.10

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management - Records Management

FDA Temporary Records Digitization Policy

Effective Date: April 6, 2022

1. Purpose

The purpose of this Staff Manual Guide (SMG) is to establish policies and high-level procedures to assist FDA Centers/Offices in the conversion of physical (analog) temporary records into reliable digital formats that safeguard, preserve, and protect FDA information and ensure document completeness and integrity, as well as the fitness of the digitized record for any purpose to which the physical record might be used. This SMG is applicable to the digitization of original records created or received in hardcopy format and are scheduled as temporary records. For the purposes of this SMG, digitization (also known as digital imaging) is defined as the process of converting any hardcopy, or non-digital record into digital (i.e., computer readable) format. This process includes capturing additional, required information, such as metadata tagging to provide basic contextual information, along with Optical Character Recognition (OCR) to enable full-text searching and management of the digital copies.

The policy and high-level procedures described in this SMG reflect National Archives and Records Administration (NARA) requirements and standards for digitizing temporary records issued in (36 CFR Chapter XII, Subchapter B, Part 1236, Subpart D). The regulation at 36 CFR § 1236.32 specifically directs that, when digitizing temporary records, agencies must meet the following standards:

- Capture all information contained in the original source records
- Include all pages or parts from the original source records

- Ensure the agency can use the digitized versions for all the purposes the original source records serve, including the ability to attest to transactions and activities

- Protect against unauthorized deletions, additions, or alterations to the digitized versions

- Ensure the agency can locate, retrieve, access, and use the digitized versions for the records entire record retention period

Under applicable regulations and the terms of this SMG, FDA digitized archival images should be searchable, but they must not be editable, in order to preserve the integrity of the records.

As part of any effort to digitize analog temporary records, FDA Centers/Offices must undertake the following steps: 1) planning for the digitization of analog temporary records belonging to the FDA Center/Office, 2) establishing requirements, 3) document preparation, 4) converting analog data and metadata capture, 5) two tier quality control validations, and 6) the retention and disposition of physical records and information. Digitized records must be stored in repositories within which the records can be readily located and from which they can be retrieved. The benefits of digitization include reduction of costs associated with records storage, accessibility, security, disaster preparedness and recovery, while it streamlines and improves overall search and retrieval capabilities.

Digitization Standard Operating Procedures (SOP) are described in detail under a separate document. Procedures identified in the Digitization SOP are recommended for use by Center/Program Offices. The Digitization SOP, when approved, will be located on the FDA Records Management Team (RMT) Records Management SMGs and SOPs SPO Site Page under the Standard Operating Procedures (SOP) section.

NOTE: This SMG does not apply to permanent records. FDA policy on permanent records will be forthcoming upon issuance of regulations by NARA on Digitizing Permanent Records.

2. Policy

To meet and comply with Federal recordkeeping laws, regulations, and guidance, to comply with applicable records schedules, and to support the FDA's own requirements and transition to electronic recordkeeping, any staff member or entity endeavoring to digitize FDA temporary records must adhere to this policy, as well as any additional internal guidance issued by their Center/Office. Other related Federal statutes, Federal guidance and FDA policies continue to apply to records and information throughout digitization. This other related material concerns, but is not limited to, issues concerning privacy, security, and Section 508 accessibility.

Creating and maintaining trustworthy records for the entire period of the applicable records retention schedule requires that Centers/Offices possess the resources needed to support the records lifecyle requirements. Centers/Offices should conduct a digitization risk analysis based on their specific situation and resources to balance the level of trustworthiness of analog records against costs, risks, and possible benefits of digitizing those records. Conducting a risk analysis is not mandatory. However, it is important that Centers/Offices evaluate the risks and costs of digitizing against risks and costs of maintenance and storage of analog records. Significant determining factors include availability of space and accessiblity of records. The level of resources used to ensure these characteristics depends on the Centers/Offices business needs and assessments of risk. The Digitization SOP, when approved, will provide criteria for conducting a risk assessment related to digitizing records. It will be located on the FDA Records Management Team (RMT) Records Management SMGs and SOPs SPO Site Page under the Standard Operating Procedures (SOP) section.

The OMB Memorandum M-19-21, "Transition to Electronic Records," issued in June 2019, requires, that to the fullest extent possible, agencies eliminate paper and use electronic recordkeeping.

The digitization methods identified in this SMG, along with the appropriate validation of those methods as required by 36 CFR 1236.30(a)(2), forms the basis for allowing FDA Centers/Offices to designate digitized images as the official record copy and thereby allow destruction of the original source record. The guidance and processes described provide minimum standards that offer Centers/Offices flexibility in how they define and conduct digitization projects to meet their specific programmatic needs. However, in order for the digitized, electronic version to replace the original, analog records, in support of FDA's mission, they must meet certain conditions to ensure that the digitized records meet the necessary standard of quality required for FDA's regulatory, legal, and public health purposes. The nature of the digitization project, the types of records being converted from analog to digital format, the resources available to perform the digitization, and the potential for a high level of public scrutiny and litigation, must all be taken into account when defining the requirements for a digitization project.

Nevertheless, in all cases, application of the digitization methodology and validation of the minimum quality standards outlined in this SMG are prerequisites for Centers/Offices to allow the destruction of original source records. Any QC process employing less than this standard will necessitate that the original physical records be retained.

This SMG also includes establishing required quality control (QC) standards that apply to all FDA digitization activities. For purposes of this policy, QC is defined as a process for ensuring the accuracy, legibility, integrity and completeness (referred to as the degree to which the record is trustworthy) of digitized records including ensuring the digitized image fully and accurately represents the physical product.

The quality approach identified in Phase 5: Quality Management below reflects the importance of performing digitization in a managed way to prevent any degradation or loss in the authenticity, reliability, integrity and usability of the records, thus ensuring an 'authoritative record' (as described in International Organization of Standardization (ISO) ISO 15489-1, Section 5). This international standard outlines the program components, planning issues, requirements, and procedures for performing the conversion and migration of digital records to preserve their authenticity, reliability, integrity and usability so that they continue to act as evidence of business transactions.

3. Authorities and References

- 36 CFR Chapter XII, Subchapter B, Part 1236 (Electronic Records Management), Subpart D (Digitizing Temporary Federal Records)
- RMT SharePoint Resources Page
- OMB Memorandum M-19-21, Transition to Electronic Records, June 28, 2019
- ISO 15489-1 (2016-04-15), Section 5 (Information and Documentation – Records Management)
- Federal Agencies Digital Guidelines Initiatives (FADGI), 2007
- FDA Master Approved Technologies (MAT) List
- NARA Universal Electronic Records Management (ERM) Requirements
- Frequently Asked Questions (FAQ) about NARA's Digitization Regulation
- SMG 3291.12, "FDA Records Destruction Policy and Procedures" (pending final approval)
- FDA Form 4081 "Certification/Approval Request to Destroy FDA Records" located in FDA On-line Forms Catalog
- FDA Records Management Master Glossary

4. Responsibilities

Director, Office of Enterprise Management Services (OEMS)

- ensures that digitized records are appropriately managed during the records creation and maintenance phases, plus final disposition is properly applied at the end of the records lifecycle; and

- authorizes and grants waivers for digitization as required.

The FDA Agency Records Officer (RO)

- develops and implements policy and procedures for Agency-wide digitization efforts, as part of the information resources management framework;

- ensures that this policy and associated procedures are communicated and referenced, as part of records management training;

- ensures that this policy is implemented and updated Agency-wide;

- ensures that any digitized record will remain available for the entire lifecycle of the relevant record, pursuant to the applicable records retention schedule;

- ensures that this policy and associated procedures are maintained as evidence of the process followed for the creation and validation of compliant digital images as records, for the life of the process or any records digitized using that process (per 36 CFR 1236.34c) ;

- reviews, makes determinations, and authorizes dispositions for unscheduled records that may be digitized;

- authorizes the revisions of existing temporary and permanent records schedules for digitized records;

- provides authority for policy and procedure review, update, and response to industry changes and associated data calls;

- ensures that FDA's Office of the Chief Counsel is consulted, as appropriate, on any plans to digitize records associated with litigation or possible litigation, as well as on high-profile matters of significant public or other interest; and,

- ensures that any contracts with outside vendors to digitize records contain appropriate provisions requiring the vendor to protect from public disclosure any FDA non-public information, including, but not limited to, proprietary data belonging to third parties.

Center/Office Director

- ensures that their FDA Center/Office adhere to this policy and its attachments;

- ensures that their Center/Office has an effective and efficient record management program that allows their employees to manage and maintain their records in all formats, in accordance with FDA Records Control Schedules (RCS);

- ensures that validated records are placed, along with required and useful metadata, into repositories within which the records and metadata can be readily located and from which they can be retrieved when they are responsive to a validly issued request for FDA documents, such an an ediscovery request or a request from Congress; and,

- incorporates digitization procedures into FDA Center/Office policy, guidance and processes, as appropriate.

Center/Office Assistant Records Liaison Officer (ARLO)

- adheres to this policy and procedures guidance, as appropriate;

- consults with Center/Office record owners on records and information as candidates for digitizing;

- consults, as appropriate, with the Office of the Chief Counsel, on any plans to digitize records associated with litigation or possible litigation, as well as on high-profile matters of significant public or other interest;

- consults with Center/Office record owners concerning the destruction of original source records after digitizing, if in compliance with the validation processes and QC standards set forth in this SMG and advises on extended retention, if warranted, based on business needs;

- consults with Center/Office record owners on the development of standard operating procedures for program specific business requirements and digitization projects, applying appropriate taxonomy and metadata standards;

- evaluates and advises record and business process owners on the retention period of digital records based on approved RCS and upon the processes of their specific Center/Office;

- participates in the development and maintenance of any additional project-specific digitization standards and procedures and ensures all relevant documents are up to date;

- consults with Center/Office record owners on digitization standards, technical specifications, and procedures for their Center/Office and other organizational groups;

- works with records, document, and content owners/generators to plan and manage the life cycle of the digitized materials;

- assists FDA personnel in implementing the procedures and related Center/Office digitization SOPs;

- advises record owners on digitization quality validation;

- advises FDA personnel to ensure that validated records are placed, along with required and useful metadata, into repositories within which the records and metadata can be readily located and from which they can be retrieved when they are responsive to a validly issued request for FDA documents, such an an ediscovery request or a request from Congress;

- authorizes and signs-off on paper document destruction in coordination with and with approval by the Center Director/Exec. Officer or a designee of the Center Director/Exec. Officer, and obtains or creates documentation verifying the destruction activity; and,

- ensures that any contracts with outside vendors to digitize records contain appropriate provisions requiring the vendor to protect from public disclosure any FDA non-public information, including, but not limited to, proprietary data belonging to third parties.

Center/Office Records Coordinator or Designated Point of Contact

- Works with appropriate ARLO to identify records to be digitized and ensures documents being scanned are records and have appropriate approved RCS.

- Adheres to this policy and procedures guidance as appropriate.

- Scans, digitizes, and indexes records.

- Ensures image is best available representation of the original.

- Ensures that validated records are placed, along with required and useful metadata, into repositories within which the records and metadata can be readily located and from which they can be retrieved when they are responsive to a validly issued request for FDA documents, such an an ediscovery request or a request from Congress.

- Tracks and maintains scanning activity data logs and performance metrics created by the Scanning Provider in a way that documents the validation process. The validation documentation must be retained for the life of the records digitized per 36 CFR 1236.34c).

FDA Chief Information Security Officer (CISO)

- implements this policy and procedures guidance as appropriate; and

- ensures the technical security of digitized records.

FDA Enterprise Architect

- ensures records management provisions are incorporated in early planning and development stages of the EPLC lifecycle.

Records Owners and Custodians

- adhere to this policy and its attached guidance, as appropriate;
- follow Center/Office guidance on digitizing records;
- obtain concurrence with the ARLO and other necesssary staff such as business process improvement or IT groups before starting a scanning project;
- inform ARLO of potential digitization projects during planning stage; and,
- create and manage digitized records, in accordance with FDA recordkeeping requirements.

Internal or External Scanning Provider

- provides scanning services to the specifications and needs of Center/Office organization(s) and adheres to all information and digitization standards detailed in Section 5 below entitled: Procedures: Conversion from Physical Media;
- documents the digitization process for audit trails for quality control purposes;
- digitizes identified records for the appropriate office;
- enters metadata, attributes, and details for each record when digitizing;
- performs optical character recognition (OCR), and quality control on all records, as required;
- performs image enhancements and virtual rescan (VRS), as needed;
- stores newly created digital records in the designated repository**;**
- performs 100% initial QC review of digitized records (either by manually reviewing images and physical source material or a hybrid approach to include software assisted QC methods in addition to Scanning Provider validation);

- ensures an acceptable digital record has been created during the digitizating process; and

- if an outside scanning provider is used, protects from public disclosure any FDA non-public information, including, but not limited to, proprietary data belonging to third parties, to which the external scanner has access during the digitization process.

NOTE: Scanning Provider can be an outside scanning vendor, in-house contract support team or FDA Staff.

5. High-Level Procedures: Conversion From Physical Media

This section defines, outlines steps,and identifies high-level procedures for the digitization of FDA temporary records. Refer to the Digitization SOP, when approved, for more detailed procedures and processes found on the RMT SharePoint Resources Page.

Digital imaging is used to preserve physical records, enhance productivity, and provide efficient storage, transfer and access to records. Digital imaging offers many advantages, including: improved distribution and publication, increased access, streamlined workflows, and a greatly reduced need for physical storage space.

Document scanning creates a static digital image/file from a physical records document. The application of optical character recognition (OCR) software must be used to create text-searchable files which increase access and use of digital images. However, the ability to alter the content must be prevented and/or disabled.

Digitization process steps include the following activities:

- Identifying, selecting, and documenting physical materials for digitization

- Preparing physical materials for scanning (including locating, preserving, gathering, reviewing for access, and screening for suitability to be digitized)

- Collecting basic descriptive and technical metadata sufficient to allow retrieval and management of the digital copies and to provide basic contextual information for the user

- Scanning and digitizing physical materials, conducting quality control (validation) of digital copies and creating metadata

- Providing access to authentic, trustworthy, reliable, and usable digital records, as well as records with integrity, for official business processes and functions for FDA Centers/Offices

- Maintaining digitized records and metadata in accordance with retention and disposition requirements

Retention and disposition of physical records, which constitutes the final step of the digitization process. Specific disposition guidance is provided in the RCS for each record series. If the source records are unscheduled, they cannot be destroyed until a records schedule is submitted and approved by NARA.

The recommended steps are grouped into six phases for digitization procedures, each of which is depicted in the following graphic. There is no standard timeline for any of the phases. The phases identified below in Figure 1 identify the various digitization stages and their corresponding activities. The phases differ according to several variables, including resources available and equipment. Details on each of the phases and their corresponding activities are described in the Digitization SOP (pending approval) and discussed throughout this Digitization SMG.

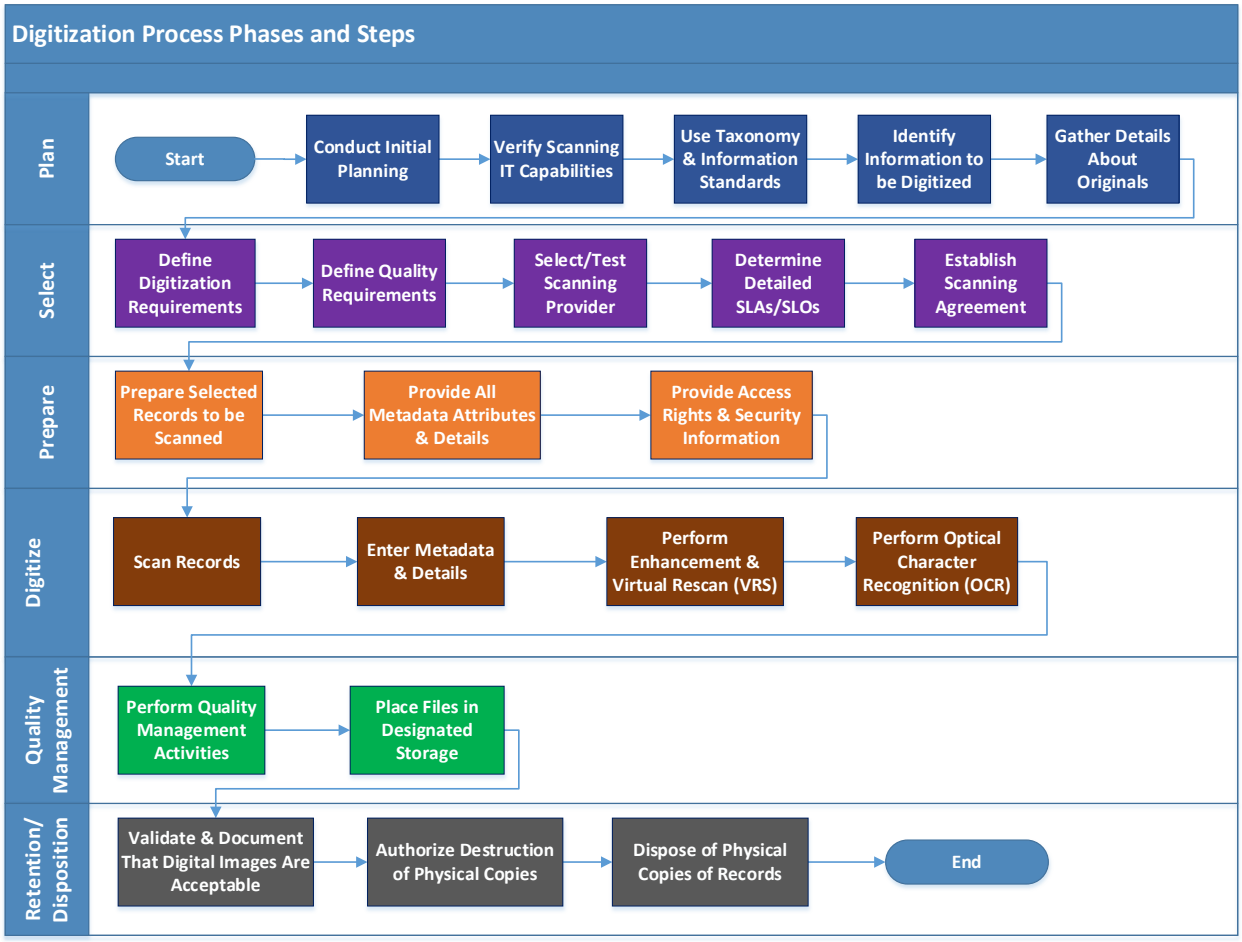


Figure 1: Digitization Process Phases and Steps

Legend: Phases are identified in bands differentiated by color (labeled with names to the left). The phases are discussed in the sections that follow.

Phase 1: Plan

Digitization can be performed in-house by FDA staff or by a contractor (onsite or off-site). Deciding on whether the scanning will be performed in-house or by a vendor should be determined early in the planning process because it may have an impact on some of the steps in the process phases. The following steps in the Plan Phase provide a comprehensive approach to digitization planning, including adherence to the Federal Agencies Digital Guidelines Initiative (FADGI) guidelines:

1. Conduct Initial Planning

   During this phase, develop the project plan and scope: the initial planning, which would include an estimate of the type and volume of records to be digitized. Project resources, such as budget (fiscal), staffing plans (human resources), etc., will be discussed and defined.

2. Verify Scanning IT Capabilities

   Whether digitization is being performed, in house, by FDA staff or via contracted services, it's very important to confirm that needed Agency space and/or IT resources are available for use in the Center/Office or by the Scanning Provider (contractor) being considered to do the work. During the Plan Phase, preliminary capability requirements should be determined:

   - Identify projected electronic storage repository
   - Confirm network capabilities
   - Identify hardware/software (in house) equipment requirements (see Phase 2 below)
   - Determine how scanned files will be transferred to the FDA repository if the scanning is performed by a vendor
   - Confirm ability to provide confidentiality/security for files for vendors

3. Use Taxonomy and Information Standards

   Determine the applicable Center/Office and/or FDA standard taxonomy of content, prior to digitizing and ingestion into electronic repositories, so retention, searches, disposition and holds can be applied effectively.

4. Identify Information to be Digitized

   Generate criteria and priorities of documents to be digitized . Several factors and questions must be addressed and answered when identifying records to be digitized, including the nature of the records, requirements for access and security permissions, retention, search capabilities, and increased efficiencies and benefits. Assess the impact on the organization and process, if records are digitized by accessing and evaluating the outcome and business case for digitization.

5. Gather Details About Originals

   The discussion below pertains specifically to born physical records. It is FDA's policy to refrain from scanning born digital records, as these records exist from inception in an electronic form. It is important to note, however, that some records exist in a combined electronic and physical state. These complex (or hybrid) records may include born digital components with born physical components such as audio or video tapes or cassettes, still photographs, microforms, and/or oversize fold down paper architectural drawings or maps.

Phase 2: Select

For each set of records to be digitized, Center/Office record owners will consider several guidelines and selection criteria, as outlined in this section. Digitization and QC requirements defined below must be met by the Scanning Provider. Record owners must consider industry best practices on quality, service, and satisfaction, to solicit and contract Scanning Provider to perform the necessary digitizating services.

1. Define Digitization Requirements

   Determine output file types, special needs and target/desired output format based on repository requirements and business needs. Consult with Center IT as needed for technical guidance; Center IT staff may consult with OIMT as appropriate. If other guidance is needed, consult with other FDA subject matter expert resources, as appropriate.

2. Define Quality Requirements

   The Center/Office must clearly document specifications and acceptance criteria for scanning output, including tools to incorporate digitization attributes, e.g. OCR, PDF, etc., and identification of minimum quality requirements and thresholds described below in Phase 5: Quality Management.

3. Select/Test Scanning Provider (In House or Offsite)

   The Center/Office must evaluate and identify the Scanning Provider services, capabilities, capacity, and processes that best suit the needs of the Center/Office and specific record collection requirements, including to determine output format(s) and delivery method capabilities of the Scanning Provider.

   The Centers/Offices need to plan strategically when determining if scanning will be done in-house or offsite. They need to evaluate the scan requirements that best suit the needs of the Center/Office and specific records collection requirements. Determining factors include, but are not limited to, volume, required resources, capabilities, capacity, standards and timeliness. The general practice is to perform high volume scanning services utilizing a contractor rather than in-house FDA staff and facilities; however, some collections may require scanning to be done on-site.

   When using in-house resources for performing digitization using FDA equipment, the FDA MAT List should be consulted and the Center/Office should request approval of scanning hardware and software from OIMT. Small-batch or ad hoc scanning activities may be best carried out by FDA employees using desktop scanners. The process of determining which scanning approach is most appropriate, is summarized in the sections below. The MAT list is searchable by key word, permitting specific scanning products to be identified. Consult with your Center/Office IT Liaison to identify specific products or types of equipment that would be appropriate.

   When possible, the Center/Office should conduct a proof of concept test for a small sampling of records to be digitized. Conducting a small proof of concept will let the Center/Office to prepare for full-scale digitization, by identifying and resolving any potential issues, any special needs or requirements, and project resource requirements and timeframes.

4. Determine Detailed SLAs and SLOs.

   Review scanning capabilities and standards, and align with quality management criteria. The Centers/Offices should outline and define Service Level Objectives (SLOs) and Service Level Agreements (SLAs).

5. Establish Scanning Agreement.

   Determine and define contract specifications and agreements.

Phase 3: Prepare

Prior to digitizing physical documents and creating an electronic version, several steps and considerations must be made. The following activities must be performed:

1. Prepare Selected Records to Be Scanned

   As an initial step, the content owner organizes and reviews physical documents and related information, archival/curatorial assessment and preparation, records description, preservation/conservation and preparation, etc. to be turned over to the Scanning Provider for scanning preparation and subsequent scanning.

2. Provide all Metadata, Attributes, and Details

   Planning for and selecting metadata for digitized records should be based on (1) the description of the content of the record; (2) the structure of the record (form, format, and relationships between record components); (3) the business context in which the record was created; (4) relationships with other records and metadata; (5) identifiers and other information needed to retrieve the record; (6) the business actions and events involving the record throughout its existence. (NARA Universal ERM Requirements).

   Centers/Offices must ensure records will follow appropriate standards including data standards, metadata schema, encoding schema, controlled vocabularies, etc. Document identifiers must have proper standardized formats and denote the various points throughout workflows, where the information/content is entered, used, and accessed.

   The Records Owner or Custodian identifies metadata to be captured, record types, where to store, and for how long The Records Owner or Custodian should then coordinate with the Scanning Provider to identify which metadata will be captured by the provider and at what stage of the process.

3. Provide Access Rights and Security Information

   Define security requirements and how the information must be secured by the Scanning Provider and submitted to FDA on media, through FDA's secure gateway or other means for placement on an FDA network after confirming access, restrictions, and security requirements have been met.

Phase 4: Digitize

The Centers/Offices must implement digitization procedures to be used to create an electronic version of physical documents and records that include scanning records, providing metadata and details. However, the electronic image cannot be editable to preserve the integrity of the record.

1. Scan Records

   Scanning Provider prepares, scans and QC's static images into digitized documents in accordance with the appropriate standards and specifications for federal records.

2. Enter Metadata and Details

   Scanning Provider enters applicable metadata and details as determined by records owner or custodian to accurately identify images.

3. Perform Image Enhancements and Virtual Rescan (VRS)

   Scanning Provider addresses legibility issues, including gray scaled images, small print, and tables for the enhanced quality of scanned images.

4. Perfom Optical Character Recognition (OCR)

   To attain full-text searchability, scanned images must be OCR'd. In addition, using technologies such as Intelligent Document Recognition (IDR) and Intelligent Character Recognition (ICR) can increase productivity and reduce cost. This allows flexibility in managing the electronic image and making the content searchable.

Phase 5: Quality Management

Throughout the scanning process and when a digitized version of the document has been created, multiple steps must be performed to examine, enhance, and validate the quality of the scan. Summarized below are the quality control activities to be performed, including: 1) automated assistance, 2) initial image QC performed by the Scanning Provider or "first pass QC," and 3) a "second pass" quality oversight and validation, performed by FDA FTEs with assistance from contractors. While the level of FTE hands-on support of QC for a specific project is left to the discretion of each Center/Office, they are ultimately responsible for oversight of the entire digitization process, and quality of the final product, and must guarantee the authenticity, reliability, integrity and usability of the records for FDA purposes. The steps include:

1. Perform Quality Management Activities

   First Pass QC - The Scanning Provider performs 100% quality control on each document and image, based on FDA policy and NARA recommendations/guidance for both completeness and digital image quality to ensure the scanned image is an accurate and complete representation of the source document.

Second Pass QC - Reviews are performed on a random sample of digitized records. Sampling size for second pass QC levels are dependent on a number of Scanning Provider and project-specific factors.

Error Rate - If more than 1% of the total number of images and associated metadata in a batch, (understood as referring here to a group of documents being aggregated by the Scanning Provider as a temporary unit for purposes of work flow control during the scanning process) are found to be defective for the reasons listed above, the entire batch should be re-inspected.

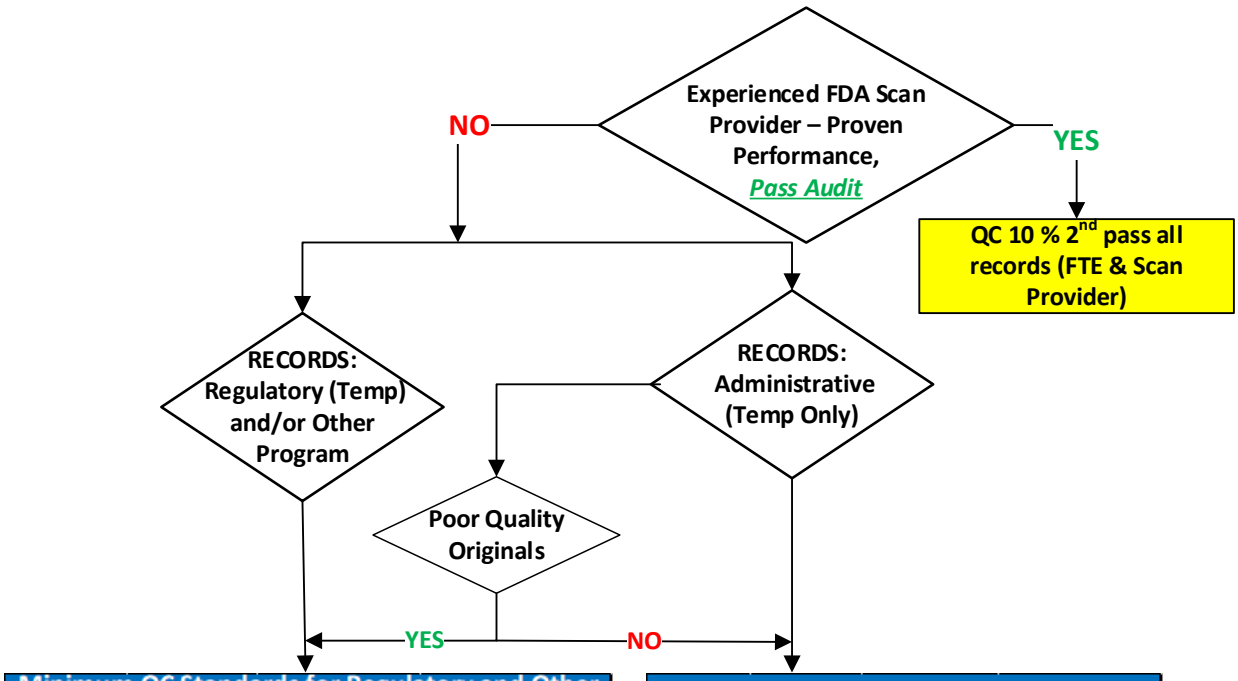
Quality Audits: An additional level of quality management is required for Centers/Offices that are conducting on-going or large-scale scanning programs. A recurring FDA audit of the operation (semi-annual) that includes a review of image quality, and other elements of the operation, such as scanning procedures, project metrics and documentation, staff training, and other applicable factors will confirm that all requirements are being met and quality is being sustained over time.

The minimum QC standards described in Figure 2 below are required for startup of new projects and contracts using a new Scanning Provider. Specific QC procedures are described in the Digitization SOP.

The QC sample required should start out at a high level during project start up [at least 75% for regulatory, 50% for administrative temporary records] to validate that the scanning and QC activities are producing digital images that meet the standards established in the Scanning Provider’s contract and SLA, and that resulting images reproduce the original source records with sufficient quality to preserve accuracy and serve as the official record copy for all FDA purposes. Other factors, such as poor quality originals, may also necessitate starting at and maintaining a higher percentage QC sample. Sampling size may be decreased over time as more pages are scanned and acceptable levels of performance and quality of results are confirmed, to a minimum of 10% based on program office business needs. However, second pass QC sampling **must** be increased when results of second pass quality reviews identify increased error rates (greater than 1%), or reveal other potential performance issues.

The QC standards described above and in Figure 2 below are required for startup of new projects and contracts using a new Scanning Provider. However, if a Scanning Provider has been performing prior work for FDA and has produced digitizing and quality reviews at acceptable levels over time, a second pass level of 10% may be performed earlier in the process, as long as the error rate had previously been found to be less than 1%. Determination of acceptable performance must be validated through an audit of the Scanning

Provider's successful past performance, as documented in project reports and production metrics.



Minimum QC Standards for Regulatory and Other Program Records			
Page Range		Level of QC	
From	To	1st PASS QC (FTE/Scan Provider	2nd PASS QC (FTE/Scan Provider)
1	6,000	100%	75%
6,001	12,000	100%	50%
12,001	20,000	100%	25%
20,001	and above	100%	10%

Minimum QC Standards for ADMIN Temp Records			
Page Range		Level of QC	
From	To	1st PASS QC (FTE/Scan Provider	2nd PASS QC (FTE/Scan Provider)
1	6,000	100%	50%
6,001	12,000	100%	25%
12,001	and above	100%	10%

Figure 2: Recommended Minimum QC Standards

Minimum QC Standards for Regulatory and Other Program Records

Pages From:	Pages To:	1st PASS QC (FTE/Scan Provider)	2nd PASS QC (FTE/Scan Provider)
1	6,000	100%	75%
6,001	12,000	100%	50%
12,001	20,000	100%	25%
20,001	and above	100%	10%

Minimum QC Standards for ADMIN Temporary Records

Pages From:	Pages To:	1st PASS QC (FTE/Scan Provider)	2nd PASS QC (FTE/Scan Provider)
1	6,000	100%	50%
6,001	12,000	100%	25%
12,001	and above	100%	10%

FDA Center/Office personnel (FTEs) overseeing the digitization project can be supported by contractors to perform second pass QC Review activities. However, FDA is responsible for validating compliance and accepting the final product.

The required QC levels must be adhered to if Centers/Offices intend to dispose of the temporary original source physical records after digitization. As previously mentioned, original permanent physical records cannot be destroyed.

2. Place Files in Designated Storage

Once the records have been converted to digital format and QC'd per step 1 (Perform Quality Management Activities), the records must be migrated to a designated storage location. It is critical to FDA records management that digitized records be preserved, located and retrievable. Identified below are requirements that must be followed for handling storage of digitized records:

- Store essential records according to the Disaster Recovery/Business Continuity plan such that digital documents are stored within appropriate repositories limiting the risk of permanent damage or destruction
- Apply controls through systems access rights
- Ensure desired searchability and accessibility of the electronic stored copy
- Store physical (paper, microform, artifact, and other) records
- Determine how long to keep the originals after digitization and whether originals for temporary records can be destroyed based on QC levels performed (see Phase 6: Retention/Disposition, Step 2 – Authorize Destruction of Physical Copies)
- Ensure there is no need for re-scan or a missed document not scanned

- Confirm with the ARLO, in conjunction with Center Director/Exec. Officer or designee, when the physical records can be destroyed

- Confirm vendor server is purged of scans upon approval after Second QC Review is complete

NOTE: As set forth earlier in this document, for any FDA Center/Office that digitizes temporary records, it is responsibility of the Director of that FDA Center/Office, as well as the Records Custodian/Point of Contact, as assisted by their ARLO, to ensure that validated, digitized records are placed, along with required and useful metadata, into repositories within which the records and metadata can be readily located and from which they can be retrieved when they are responsive to a validly issued request for FDA documents, such an an ediscovery request or a request from Congress.

Phase 6: Retention/Disposition

NARA grants FDA Centers/Offices the authority to dispose of temporary original source records and to replace them with digitized versions that have been validated in accordance with the standards prescribed in (36 CFR Chapter XII, Subchapter B, Part 1236, Subpart D and General Records Schedule (GRS) 5.2, Item 20, Intermediary Records. The following are digitization guidelines that must be followed relating to validation and disposal:

1. Validate and Document that Digital Images are Acceptable

   ARLO confirms with the Business/Records Owner or Project Point of Contact that the digitized records meet all the purposes and are of suitable quality to replace the original source records.

2. Authorize Destruction of Physical Copies

   Destruction of temporary physical copies is permissible with the ARLO and the Center/Office Senior Management approval and when the QC guidelines set forth in this SMG have been followed and acceptable copies have been validated at the levels specified. If the Center/Office does not perform QC and validation of acceptable digital copies, in accordance with the minimum standards outlined in this SMG, then the Center/Office must retain and store the paper source documents. Physical records that have been digitized prior to the effective date of this SMG may be destroyed, if the Center/Office has validated that the records have been digitized and QC'd to meet quality standards that are consistent with the standards outlined in this SMG and 36 CFR Chapter XII, Subchapter B, Part 1236, Subpart D.

   Original source records may be destroyed after the digitized records have been saved (and verified) to an FDA-approved electronic recordkeeping

system or other electronic repositories approved for storing FDA records, and it has been determined that the physical records are not needed for Agency business and there are no administrative, audit, legal and/or operational requirements such as formal information requests, records holds or freezes on the records. Temporary records that have reached the end of their retention period and are no longer needed, must be disposed of, following instructions specified in the applicable FDA RCS and SMG 3291.12, "FDA Records Destruction Policy and Procedures" (draft pending approval).

The ARLO, with concurrence from the Center/Office Director or designee, must ensure that a "Certificate of Destruction" is signed by the destruction provider and a copy is saved as a record for documentation of the respective destruction.The responsibility for providing the certificate to the Center/Office is on the entity that performs the destruction. Additionally, a Destruction of Records Form is available in the FDA On-line Forms Catalog for FDA Form 4081 "Certification/Approval Request to Destroy FDA Records".

3. Dispose of Physical Copies of Records

   Centers/Offices can destroy physical record copies following established FDA secure destruction procedures.

   Please consult with Center/Office ARLOs if there are any questions or special cases concerning digitized records.

6. Glossary

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

7. Effective Date

The effective date of this guide is April 6, 2022.

8. Document History - SMG 3291.10, "FDA Temporary Records Digitization Policy"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	02/18/2022	N/A	OO/OEMS/DIG	Tiffany Branch, Director, OO/OEMS

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