Sections in This Document

1. Purpose

To assure that records used by laboratory employees are properly managed. Records include reports, correspondence, quality records and technical records. Quality records include the following: internal audit reports, management reviews, corrective and preventive actions, etc. Technical records include data, forms, worksheets, control graphs, test reports, etc.

2. Scope

This procedure applies to the Office of Regulatory Science (ORS) laboratories and laboratory work products and processes. This procedure directly concerns the laboratory's quality assurance program and applies to the management of ORS laboratory records identification, collection, indexing, access, filing, storage, maintenance and disposal. Records may be either in hard copy or electronic form.

3. Responsibility

A. Laboratory Management

1. Verifies the accuracy of records.
2. Ensures employees are trained in record keeping policy and procedures.
3. Follows established record storage and disposal schedule.

B. Quality System Manager (QSM):

1. Maintains quality record system.
2. Ensures archival and disposal of quality records by record schedule.

C. Record Coordinator:

1. Oversees the management of unit records in accordance with ORA-ORM.018 ORA Records Management Program.
2. Conducts annual record inventory.
3. Facilitates and ensure proper records maintenance, storage, disposal, retrieval, or transmittal (hardcopy and electronic);
4. Monitor records control; at a minimum conduct or coordinate annual audit of records control processes within the assigned Center/Office and document results. Coordinate and/or issue request for corrective action. Records/records management audit may be conducted in conjunction with system, procedure or process audits. Reference SMG 2020;
5. Participate and/or conduct local records management training.

D. Staff:

1. Responsible for following record management guidelines.

4. Background

None

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories. Sections 8.4, 7.5, and 7.11

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals; An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

C. SOP-000114, Control of Quality Records

D. SOP-000220, ORA Records Management Program

6. Procedure

6.1. Record Identification

A. Records are identifiable to the firm, product, person or event to which they pertain. Records are dated and identify the person who established the record.

B. Laboratory records contain sufficient information to maintain an audit trail (see Attachment B)

6.2. Recording and Error Correction

A. Electronic records within information management systems have audit trails to track changes and corrections.

B. All work performed is recorded legibly. Work is recorded in such a manner that another individual, competent in the same field, may repeat the work described solely from the description written without additional explanation.

C. Entries contain the date and initials or date and signature of the person performing each laboratory activity and reviewing data and results . Electronic entries in data recording systems such as Field Accomplishments and Tracking System (FACTS), Quality Management Information System (QMiS) or other electronic tracking system provide an audit trail.

D. If entries are not electronic, they are made in ink. No erasures or obliterations are made. Space not used are indicated with a line.

E. Corrections are made by drawing a single line through the incorrect entry, entering the correct information, and initialing and dating the change.

Electronic entries in data recording systems such as an electronic tracking system provide an audit trail of changes.

F. Data or information is not discarded without explanation. Both original and amended data must be retained. To discard, the data or information is crossed out, initialed, dated and the reason for discarding indicated. Electronic entries in data recording systems provide an audit trail or require comments for data that is not used.

6.3. Electronic Records

A. Electronic records and data files are backed up on a regular basis to safeguard against the loss of information due to equipment malfunctions or human error.

B. Access to backup records are periodically confirmed and a record of the periodic confirmation is retained. See local procedures for specific policy, procedures, and schedules.

C. External labels of disk and diskettes or CDs are labeled to facilitate accurate filing and retrieval of electronic records. Examples of information that may be included on the label are:

1. subject or functional title which identifies the information,
2. inclusive dates of information contained on the diskettes or CDs, and
3. identification of the software program used to access the information.

D. Laboratories periodically confirm access to backup records according to local procedures.

6.4. Access

Access to records is restricted to prevent unauthorized use and amending of information. See local procedures for specific policy and procedures.

6.5. Filing and Storage

A. Records are kept on the premises and secured (e.g. in a cabinet or drawer) when not being actively used.

B. Records are stored in dry and clean locations. Storage areas and cabinets are labeled. Records may not be stored in obscure locations that are not identified. See local procedures for specific policy and procedures for how and where records are filed and stored

C. Analytical worksheets are submitted to the collecting program area and not stored by the analyzing laboratory in general. Electronic reports and records of laboratory data are maintained in the applicable web application, such as Field Accomplishments and Compliance Tracking System (FACTS),

electronic tracking system, Scientific Data Management System (SDMS), etc.).

D. Backup records are stored in a separate location from the original records.

6.6. Record Retention

A comprehensive description of FDA record retention policy is described in SOP-000114 Control of Quality Records and SOP-000220 ORA Records Management Program.

A. Attachment A is the general laboratory records schedule.

B. Additional policy and procedure may be found in local procedures.

6.7. Disposal of Records

After the retention period has expired records are destroyed or transferred to an agency storage facility, for example, the Federal Records Center (FRC). Disposal of documents is in accordance with guidelines described in agency policy statements and directives.

6.8. Archival of Documented Procedures

A. Superseded and outdated laboratory operating procedures and work instructions (controlled copies), etc. are removed from accessible locations and archived. Records may be labeled as “Archived” or “Obsolete.”

B. Master lists are updated.

6.9. Other Quality Records

Quality records (e.g. audit reports, reviews, function verification and preventive maintenance charts, quality control charts, corrective actions) are periodically archived. Best practice is to archive per calendar year or fiscal year. Local procedures should specify the schedule.

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7. Glossary/Definitions

A. Archive – process of moving records or electronic files that are no longer actively used or current to a location for retention for a defined period.

B. Records Cut Off is a file break, or ending of files at regular intervals, usually at the close of a fiscal or calendar year or when a case is closed. Records Cut Off is used to start the retention period for a record.

C. Data file – A data file is related numeric, graphic or textual information that is organized in a strictly prescribed form and format.

D. Electronic record – An electronic record is information recorded in a form that only a computer can process. Electronic records include numeric, graphic and textual information.

E. Form – A form is a document with a fixed arrangement of captioned spaces designed for entering and extracting prescribed information. Forms become a record once filled out.

F. Non-record – Non-records are copies of memoranda or letters sent to an office or an employee for information only and for whose filing or maintenance no one in the office is responsible.

G. Records – Records are materials created or received by an agency and that are preserved as evidence of the activities of the agency or for its information value.

H. Records Control Schedule - provides mandatory instructions and authority on how long to keep records (retention) and when they can be destroyed and/or transferred to alternate storage facilities or NARA Archives (disposition).

I. Retention time – Period or amount of time records are kept before disposal/destroyed or archival. Starts at the time the record cutoff has been reached.

J. Technical records – Technical records are accumulations of data and information which result from carrying out tests or calibrations and which indicate whether specified quality or process parameters are achieved.

K. Controlled copy – A controlled copy is a document that is numbered and issued to an individual, the contents of which will be updated after distribution.

L. Uncontrolled copy – An uncontrolled document is a document that is current at the time of issue but for which no attempt will be made to update it after distribution; document is marked “Uncontrolled Copy”.

8. Records

A. Field Accomplishments and Tracking System (FACTS)

B. Laboratory Information Management System (LIMS)

C. Quality Management Information System (QMiS)

9. Supporting Documents

None

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.3	R	12/31/07	LMEB	LMEB
1.4	R	6/6/08	LMEB	LMEB
1.5	R	2/21/12	LMEB	LMEB
1.6	R	03/25/13	LMEB	LMEB
1.7	R	05/08/14	LMEB	LMEB
02	R	05/15/2019	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change
02	Referenced ORA-QSM.002 and deleted the redundant statements from old revision. Removed staff manual guide reference. Added QMiS. Added reference to see local procedures for specifics of filing and storage. Other revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were made.

12. Attachments

List of Attachments

Attachment A - Laboratory Record Control Schedule

Laboratory and related records, retention periods, and disposal, are maintained as follows:

Record	Cutoff	Retention/Disposal	Schedule #
Purchase Records for transactions that exceed the simplified acquisition threshold	Final Payment	Destroy 6 years and 3 months after cutoff	FDA 9521a
Purchase Records for transactions at or below the simplified acquisition threshold	Final Payment	Destroy 3 years after cutoff	FDA 9521b
(LIMS/FACTS, etc.) Program Database Records Include sample data, lab results, comments	End of Fiscal year after final action	10 years after cutoff	ORA 3230
System Documentation (includes system & user manuals, data dictionary, requirements for ORA Reg. dBase Mgt. & support activities)	Temporary	When superseded or obsolete	ORA 3250
Violative Lab worksheets (Domestic)	End of fiscal year after reg. decision.	5 years after cutoff	ORA 6120
Violative Lab worksheets (Imports)	End of fiscal year after re-exportation	5 years after cutoff	ORA 4130
Non-Violative Lab worksheets (Domestic)	End of FY after regulatory decision	2 years after cutoff	ORA 6110
Non-Violative Lab worksheets (Imports)	End of FY upon release	2 years after cutoff	ORA 4110
Pre-Market/Pre-Approval Lab Test Records (includes analytical worksheets, lab test results summary report, attachment for lab control documents for NDA, ANDA, NADA)	End of fiscal year after final action or analysis	10 years after cutoff	ORA 6210
Lab test records not related to preapproval/premarket evaluations. (includes analytical worksheets, lab test results summary report, attachment for lab control	End of fiscal year after final action or analysis.	5 years after cutoff	ORA 6220

Record	Cutoff	Retention/Disposal	Schedule #
documents not related to NDA, ANDA, NADA)			
Shelf Life Extension Program (SLEP) raw data	End of calendar year when entire lot testing is completed.	10 years after cutoff	ORA 2423
Lab QA Records (lab notebooks, instrument calibration, growth media, QC chart, Mgt Review, CAPA, DCRs, Complaints/Feedback, Audit Records, transmittal notices, etc.)	End of fiscal year after final action	3 years after cutoff	FDA-4300
Method validation/verification records	Cutoff at end of FY when method is no longer used.	Delete/destroy 3 years after cutoff	FDA-4300
Analytical Training Records	Cutoff: end of FY after employee leaves.	Delete/Destroy 5 years after cutoff	FDA 4913
Check Sample Analytical Packages (Worksheets, printouts from analytical instruments, & other related records that show analytical findings.)	End of the fiscal year after the Final Report is completed.	Destroy/delete 3 years after cutoff	ORA 6310
Final Check Sample Reports	End of FY after Final Report completed	Delete/Destroy 5 years after cutoff	ORA 6320
National Check Sample Program (NCSP) Annual Schedule	End of FY after completion of check sample analysis.	Delete/Destroy 5 years after cutoff or when no longer needed for reference, whichever is later	ORA 6330
NDA – New Drug Application ANDA – Abbreviated New Drug Application NADA – New Animal Drug application QA/QC – Quality Assurance / Quality Control			

Attachment B - Requirement for an audit trail in laboratory records includes the following:

A. Analyst(s) performing steps in the testing process
B. Analyst training → with traceability to Reference Materials (RMs) and proficiency checks
C. Calibration records → with traceability to suitable RMs
D. Column lot number
E. Equipment performance → (e.g., using CRMs, proficiency checks, and daily checks)
F. Equipment qualification and maintenance
G. Equipment used (*see Note*)
H. Media/Reagent identity
I. Media/Reagent open date when open date impacts expiration date
J. Media/Reagent/Reference material expiration date
K. Media/Reagent/Reference material laboratory assigned identification
L. Media/Reagent/Reference material lot number
M. Media/Reagent/Reference material received date
N. Prepared media/reagent preparation date
O. Prepared media/reagent preparer
P. Prepared reagent components
Q. Prepared reagent special instruction, hazards, or use restrictions
R. Reagent concentration/purity
S. Reports (mailed or electronic)
T. Results
U. Review of electronic transmissions [e.g., Laboratory Information Management Systems (LIMS) acquisitions)]
V. Reviews
W. Sample analysis (raw data including chromatograms, standard curves, etc.)
X. Sample handling and storage
Y. Sample preparation

Z. Sample receipt (log-in/check-in)