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Sections Included in this Document and Change History

1. Purpose/(revised)
2. Scope
3. Responsibilities/(3.D.revised 2nd bullet; E. revised last two bullets)
4. Background
5. References
6. Procedure/(6.2 B.2.-5., C. 1., E. 4. & 5., G. 1. & I 1. & 2. Revised)
7. Definitions
8. Records
9. Supporting Documents
10. Attachments/Record Schedule updated)
11. Document History

1. Purpose To assure that records used by [Name] 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. Technical records include forms, worksheets, control graphs, and test reports.

2. Scope This procedure applies to the management of records within the [Name]. Records may be either in hard copy or electronic form.

3. Responsibilities


A. [Third Level Manager]:

- verifies adequacy and accuracy of forms and worksheets used in their area,
- reviews report packets for completeness, and
- ensures employees are trained in record keeping.

B. [Second Level Manager]:

- implements record management system in respective branch,
- ensures proper forms and worksheets are used in respective branches, and
- follows established record storage and disposal schedule.

C. [First Level Manager]:

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- ensures implementation of a record management system,
- ensures storage areas for records are within resources, and
- periodically assess the effectiveness of the record management system.

D. Quality System Manager (QSM):

- maintains record system for quality records, and
- ensures archival and disposal of quality records as established by record schedule.

E. Record Clerk (Optional):

- maintains record system and databases,
- transfers records for archival as established by record schedule, and
- serves as principal custodian for the Records Management Center (RMC).
- In the absence of the record clerk, alternates are appointed. The alternates are responsible for checking in and out of records only.

F. Staff is:


- responsible for using the proper and approved forms and worksheets,
- responsible for following record management guidelines, and
- securing records (i.e. placing in locked cabinets) when in their possession.

4. Background

None.

5. References

Staff Manual Guide FDA SMG 3291.2, Field Office Filing System

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**6.
Procedure**

Procedure for identification, collection, indexing, access, filing, storage, maintenance and disposal.

A. Record Identification


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

B. Recording and Error Correction

1. 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.
2. Entries contain the date, initials of person performing the work, signature and date. Electronic entries in data recording systems such as Field Accomplishments and Tracking System (FACTS) or Laboratory Information Management System (LIMS) provide the date, identification of person performing the work, and electronic signature with date.
3. If entries are not done electronically, entries are made in ink. No erasures are made. Space not used will be indicated with a line.
4. Corrections will be made by drawing a single line through the incorrect entry, enter the correct information, initial and date the change. Electronic entries in data recording systems such as LIMS provide an audit trail of changes.
5. Data or information is not discarded without explanation. 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.

C. Electronic Records

1. 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. Instrument backups are noted on the

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respective Function Verification and Preventive Maintenance sheet, equipment log, or documented by the Scientific Data Management System (SDMS) if performed automatically using Symantec BackupExec.


2. If applicable backups for the database in the Records Management Center (RMC) onto tape media are performed daily, weekly and monthly.
3. 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:
 - subject or functional title which identifies the information,
 - inclusive dates of information contained on the diskettes or CDs, and
 - identification of the software program used to access the information.

D. Access

1. There is restricted access to all records to prevent unauthorized use and amending of information.
2. Access to the [Name] is restricted to authorized personnel ([Name] personnel or escorted visitors.
3. Records are returned during normal business hours to principal custodian or alternates.
4. Records to be filed in the [Location] are secured in the room at all times. This includes records that have been returned.
5. Electronic records have password or field protection, or read-only capabilities.

E. Filing and Storage

1. Records are stored in dry and clean rooms. Storage areas and cabinets are labeled. Records and other quality documents may not be stored in private desk drawers or other obscure locations that are not generally

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known.


2. Records pertaining to completed applications are filed in the [Location].
3. Records are filed by the [Filing Convention (e.g. sample identification number)].
4. Quality records (e.g. audits, archived procedures and work instructions, corrective action and problem reports, function verification and preventive maintenance charts) are filed in the Quality System Manager's office or archived electronically by the appropriate web application, such as Quality Management Information System (QMiS) or Laboratory Information Management System (LIMS).
5. Analytical worksheets except for Lab Class I microbiology import samples are returned to the home district 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), Laboratory Information Management System (LIMS), Scientific Data Management System (SDMS), etc).

F. Record Charge-Out

1. To charge out a record, [Procedure].
2. Records that are charged out are kept on the premises and kept secured (e.g. in a cabinet or drawer) when not being actively used.
3. To transfer a charge-out record, the file is returned and then transferred to the requested person.

G. Record Retention

1. The retention period will not be less than five years or as governed by regulation or policy. Quality records will be retained for a minimum for three years. LIMS database records are retained for a minimum of 10 years.
2. Reports will be stored in a secure location with limited access. Computer based files are archived and stored for record keeping.

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3. The following information should be available in laboratory data files:

- date, place, time of sampling and name of person who collected,
- identification of sample as to whether it is a routine or check sample,
- date of receipt of sample and date of analysis,
- laboratory and persons responsible for performing analysis,
- analytical technique and method used and quality control data, and
- results of analysis.

H. Disposal of records


After the retention period is completed records will be 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.

I. Archival of Quality Records

Laboratory Operating Procedures

1. Superseded and outdated laboratory operating procedures and work instructions (controlled copies) are archived and replaced. QMiS performs this automatically. Archived hardcopy records are marked "ARCHIVED", dated and filed for the remaining time of the retention period.
2. The master list is updated and electronic files are moved to a directory titled "ARCHIVEDSOPS" or moved to the Archive vault in QMiS which performs this function automatically.

Other Quality Records

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1. Quality records (e.g. audit reports, reviews, FV and preventive maintenance charts, quality control charts, corrective actions) are archived per calendar year. Only current year's records are kept in the applicable areas. Electronic records are accessible and archived in the appropriate web application, such as QMiS or LIMS.

7. Definitions

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

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.

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.

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.

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.

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.

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.


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

None

9. Supporting Documents


None

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10. Attachment A: Record Schedule
Attachments

Document History					
Version No.	Status (I, R, C)	Date Approved	Location of Change History	Name & Title	
				Author	Approving Official
1.3	R	12/31/07	In Document	LMEB	LMEB
1.4	R	6/6/08	In Document	LMEB	LMEB
1.5	R	2/21/12	In Document	LMEB	LMEB
1.6	R	03/25/13	In Document	LMEB	LMEB
1.7	R	05/08/14	In Document	LMEB	LMEB

Approving Official's signature: _____ Date: _____

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Laboratory and related records, with their storage locations, retention periods and disposal, are maintained as follows:

Record	Retention	Disposal	Schedule #
LIMS Database Records (includes sample data, laboratory results, comments)	End of fiscal year after final action	10 years after cutoff	ORA 3230
Output Records (includes data extracted periodically For reports)	Temporary	When no longer needed	ORA 3240
System Documentation (includes system and user manuals, data dictionary, Requirements)	Temporary	When superseded or obsolete	ORA 3250
Laboratory Test Records, Reg. (includes analytical worksheets, lab test results Summary report, attachments For lab control documents)	End of fiscal year after final action or analysis	5 years after cutoff	ORA 6220
Non-Violative Lab worksheets (Imports)	End of fiscal year upon release	2 years after cutoff	ORA 4110
Non-Violative Lab worksheets (Domestic);(includes labeling, Seal integrity & other documentation)	End of fiscal year after reg. decision	2 years after cutoff	ORA 6110
Violative Lab worksheets (Imports)	End of fiscal year after re-exportation	5 years after cutoff	ORA 4130
Violative Lab worksheets (Domestic)	End of fiscal year after reg. decision	5 years after cutoff	ORA 6120
Pre-Market/PreApproval 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
Shelf Life Extension Program Records (analytical worksheets)	End of calendar year when entire lot testing complete	10 years after cutoff	ORA 2422
Lab QA Records (includes lab notebooks, instrument calibration, validation, growth media, lab procedures, QC charts)	End of fiscal year after final action	3 years after cutoff	FDA 4300

NDA – New Drug Application; ANDA – Abbreviated New Drug Application;NADA – New Animal Drug Application;
 QA/QC - Quality Assurance/Quality Control