[Organization logo]

[Organization name]

Commented [170251]: All fields in this document marked by square brackets [ ] must be filled in.

DOCUMENT AND RECORD CONTROL PROCEDURE

Commented [170252]: If you want to find out more about control of documents, see:

New approach to document and record control in ISO 9001:2015 http://advisera.com/9001academy/blog/2015/06/30/new-approach-to-document-and-record-control-in-iso-90012015/

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [170253]: Adapt to the existing practice in organization.

Distribution List for Paper-based Documents

Commented [17A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy No.	Distributed to		Date	Signature	Returned	
					Date	Signature

Change History

Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

Table of Contents

1. Purpose, Scope and Users

The purpose of this procedure is to ensure control over the creation, approval, distribution, usage, updates, retention, and disposition of documents and records (also called "documented information") used in the QMS (*Quality Management System*) for performing [testing and/or calibration] laboratory activities.

This procedure is applied to all documents and records related to the QMS of the laboratory, regardless of whether the documents or records were created inside [organization name] or whether they are of external origin. This procedure encompasses all documents and records containing information and data, stored in any possible medium – digital or paper.

Users of this procedure are all personnel that perform laboratory services and recording results of laboratory activities identified under the laboratory's scope as documented in the Quality Manual.

2. Reference Documents

- ISO/IEC 17025:2017, clauses 7.5, 7.11, 8.2.1, 8.3, 8.4
- Quality Manual
- [other documents and regulations requiring document control]

3. Control of Documents

Internal documents are all documents created inside the organization (e.g. policies, working instructions, etc.). Internally created documents are listed by [Job title] in the List of Internal [illegible] while records are listed on the List of Types of Records.

[illegible] must have a document owner who is competent to review and update the subject matter of the document.

3.1. Creation and identification of documents

[Job title] ensures that all documents are identified by name, code, date of version, version number) and copy number.

Identification of documents is performed as follows:

- [illegible] are coded in the following way: [describe the organization's standard practice].
- [illegible] are coded in the following way: [describe the organization's standard practice].

Commented [170255]: Insert the proper laboratory activity for your organization.

Commented [17A6]: You will find this document in the ISO 17025 Toolkit folder "03_Quality_Manual".

Commented [17A7]: The designated person responsible for the document control process or the document owner.

Commented [17A8]: The designated person responsible for the document control process or the document owner.

Commented [170259]: Procedures are coded with four alphanumerical characters: PR.XX

The coding is as follows:
- PR – Letter marking of type of document – e.g. PR stands for procedure
- XX – Numerical marking – ordinal number of procedure in ascending order

Commented [1702510]: Records are coded with five alphanumerical characters: PR.XX.Y

[illegible]

The documents within the scope of the QMS are formatted in the same way as this document.

3.2. Document approval

All documents, regardless of whether they are new documents or new versions of existing [redacted] for suitability and adequacy.

[redacted] are approved by signature of paper documents or other [redacted] using electronic documents.

3.3. Publishing, distributing and accessing documents

After approving a draft or a new version of a document, [job title] keeps the original version and distributes the numbered copy to the place of use.

[redacted] issuance.

3.4. Withdrawal of outdated documents

The new version of a document is immediately distributed to the place of use upon creation and [redacted] document is destroyed or labeled "Replaced by version number" if it is intended to be archived as a reference. If using electronic documents, when there is an older version of the document, [job title] [redacted].

[redacted] decides whether the outdated document should be archived or destroyed and the method of destroying the document.

3.5. Document updates and changes

The person listed as the document owner has the responsibility for updating and changing the document. Updates and review are performed periodically at least once per year or whenever it is [redacted] to the document and distribution are done by the [redacted].

Commented [1702511]: Review and approval should be done by a senior member of the laboratory staff with the document owner.

Commented [1702512]: In case there are several document [redacted]

Commented [1702513]: Alternatively, if using electronic documents, you can define that the document is approved by email, or by changing its status in the document management system.

Commented [1702514]: The designated person responsible for the document control process or the document owner.

Commented [1702515]: The designated person responsible for the document control process or the document owner.

Commented [1702516]: Folder name could be "Archive" or "Withdrawn documents".

Commented [1702517]: The person who is responsible for the document control process or the document owner.

Commented [1702518]: Person assigned to the document control process.

All changes to the document should be made using "Track changes," making visible only the revisions to the previous version and briefly described in the "Change History" table. If the Track changes [illegible]

3.6. Documents of external origin

Each external document that is necessary for the laboratory operations must be identified by [Job title] in the List of External Documents. Document title, date, and revision level must be included [illegible]

[illegible]

4. Control of Records

[Job title] uses the List of Type of Records to identify the records by their type. Record owners are identified under the column "owner" in the List of Type of Records. Record owners must ensure that [illegible] to records must be consistent with confidentiality arrangements. If the sensitivity of certain records is such that permission for access must be obtained from a different person, this must be stated in [illegible]

[illegible]

If there are changes to such records, [Job title] ensures that both the original and changed records are kept, in a legible format, along with information about the change (who, what, and when). [Job title] [illegible]

[illegible] and method for destroying obsolete records and documents, as guided by industry standards and [illegible]

Commented [1702519]: The person who is responsible for the document control process or the document owner.

Commented [1702520]: The person who is responsible for the document control process or the document owner.

Commented [1702521]: An administrative function assigned to a trained and qualified employee.

Commented [1702522]: An administrative function assigned to a trained and qualified employee.

Commented [1702523]: An administrative function assigned to a trained and qualified employee.

Commented [1702524]: An administrative function assigned to a trained and qualified employee.

Commented [1702525]: An administrative function assigned to a trained and qualified employee.

Additional instructions may be needed for some electronically stored records.

5. Managing Records Kept on the Basis of this Document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
List of Internal Documents	PR.00.1	Older versions are archived for 3 years	[office of [job title]	Records are stored in file cabinet or in personal computer [describe name/location]	[job title]
List of External Documents	PR.00.2	Older versions are archived for 3 years	[office of [job title]]	Records are stored in file cabinet or in personal computer [describe name/location]	[job title]
List of Type of Records	PR.00.3	Older versions are archived for 3 years	[office of [job title]]	Records are stored in file cabinet or in personal computer [describe name/location]	[job title]
Registry of Records for Retention/Central Archive	PR.00.4	Older versions are archived for 3 years	[office of [job title]]	Records are stored in file cabinet or in personal computer [describe name/location]	[job title]

Only [job title] can grant other employees access to the records.

Commented [1702526]: Adapt the information in these columns to the normal practice in your laboratory.

Commented [1702527]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [1702528]: The laboratory manager or document owner.

6. Appendices

- Appendix 1 – List of Internal Documents
- Appendix 2 – List of External Documents
- Appendix 3 – List of Types of Records
- Appendix 4 – Registry of Records for Retention/Central Archive