DOCUMENT MANAGEMENT PROCEDURE

Created by	Verified by	Approved by
(Insert role)	(Insert role)	(Insert role)
(Insert name)	(Insert name)	(Insert name)

Rev.	Date	Description of the change
1	XX/XX/XXXX	First review
2	XX/XX/XXXX	Added in the scope the process of ABCDEF
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1.0 Purpose

The management of all documents of the Quality Management System (QMS) is controlled and actively monitored to ensure that:

- All documents are adequately identifiable, traceable, and available at consultation and/or usage centers in their most up-to-date revisions.
- Documents that are no longer valid (obsolete) are promptly removed from these centers to prevent unwanted or inappropriate use.
- Records can provide the necessary evidence of activities

This process aligns with the requirements outlined in Clause 7.5 of ISO 9001:2015: "Documented Information."

2.0 Scope

This procedure applies to all documentation and records, whether in paper or electronic format, within the Quality Management System

3.0 Terms and definitions

- QMS document list: this document is the list of all the procedures, instructions and forms of the QMS.

Additionally, the section titled "External Origin Documents," contains a list of laws and voluntary standards that the Company has assessed as relevant.

- Quality Documents: documents necessary for the QMS that need to be checked at least once a year during the Management Review. These documents all start with a “00” code.

Example: quality policy

- Procedures (PRO) and Instructions (INS): These documents describe the processes of the Organization, defining operational methods, resources, and responsibilities to ensure process control.

Example: Provider evaluation procedure

- Forms (FRM): These documents are the blank version of documents that need to be created.
  Example: providers evaluation form
- Records: all the documents that are a result of a process are technically records.

Example: all compiled forms are records.

- External Origin Documentation: these are the documents that have not been created by the Organization, but need to be kept by the Organization in an orderly way.
  Examples:
  - Technical data sheets for products and tools
  - Standards, laws, and directives
  - Contracts

4.0 Process

4.1 Documents life cycle

4.1.1 Creation

The first draft of procedures, instructions and forms could be performed by any employee. Usually this task is assigned to the Manager of that area, since he/she is the person that knows the process best.

The name of the Employee that did the created the first draft is written in the “Created by” column.

4.1.2 Verification

Drafts of procedures, instructions, and forms may be subject to verification by another employee when necessary, a practice referred to as the '4-eyes principle.' The name of the verifying employee is recorded in the 'Verified by' column.

If there is no other employee in the company with the required expertise to perform the verification, the document may be verified by the same person who created it.

4.1.3 Approval

The approval of the document is done by the CEO of the company.
(insert here the name of the higher person in your organisation).

4.1.4 Expiration

When a specific procedure, instruction, or form no longer accurately reflects the current process due to process changes, it must be marked as expired.

There are two options:

- Create a new, updated version with a new revision.
- Do not create a new document.

Expired documents are archived by the Quality Specialist in a dedicated folder and removed from the List of QMS documents.

Procedures, instructions, and forms have a maximum validity of 5 years. After this period, they undergo a review. Even if they remain valid, a new revision is created, and a comment is added in the 'revision section' to indicate that the document has been reviewed. (Please note: the rule about the maximum revision date of QMS documents can be different. Every company has to pick their own rules. A 3 years cycle or a 10 years cycle are also technically possible, for example)

4.2 Coding

Before their official approval, QMS documents are assigned an unique code to ensure traceability. Each QMS document is uniquely identified by:

- An alphanumeric code.
- A revision number.
- A date

4.3 Distribution

QMS documents are shared with the relevant interested parties. This activity is a responsibility of the Quality Specialist.

The quality Specialialist is also responsible for monitoring that outdated revisions of documents are not used.

4.4 Storage

All QMS documents are stored in the official repository, which is a folder in the Company server.

The signed version of procedures and instructions is kept by the Quality specialist in a physical storage in his/her office space.

(please note: describe in this chapter where your company keeps the files of the QMS. This part is very specific of your company and therefore cannot be described in detail in templates)

5.0 Records

The archiving of Records is done as specified in the following table.

Records	Minimum years of retention
Risk assessments	10 years
Legal requirements and legal compliance audits	10 years
Non-conformities, corrective actions	10 years
Training and/or educational activities	10 years
Internal and external communications	5 years
Expired revisions of QMS documents	5 years
Management Reviews	10 years
Machinery maintenance	10 years
Documentation on Occupational Health and Safety	10 years

(please note: this is an example – you should pick your frequency according to the needs and risks of your Company)