[Organization logo]

[Organization name]

Commented [AS91001]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR DOCUMENT AND RECORD CONTROL

Commented [AS91002]: If you want to find out more about control of documents, see:
New approach to document and record control in AS9100
https://advisera.com/9100academy/knowledgebase/new-approach-to-document-and-record-control-in-as9100/

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

Commented [AS91003]: Adapt to the existing practice in organization.

Distribution list

Commented [AS91004]: 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	9100Academy	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this procedure is to ensure control over creation, approval, distribution, usage, updates, retention, and disposition of documents and records (also called: documented information) used in the QMS (*Quality Management System*).

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

This procedure doesn't apply to documents and records regarding [describe the parts of organization that this procedure doesn't apply to].

Commented [AS91005]: E.g. Finance, accounting, general and legal affairs.

Users of this document are all employees of [organization name] inside the scope of the QMS.

2. Reference documents

- AS9100 Rev D, clause 7.5
- Quality Manual
- Scope of Quality Management System
- [other documents and regulations specifying document control]

Commented [AS91006]: If documentation is managed electronically define data protection processes.

For example:

[redacted]

3. Control of documents

Internal documents are all documents created inside the organization, e.g. policies, working instructions, records etc., and are listed on the List of Types of Records.

Commented [AS91007]: For example:

Procedures are coded with four alphanumerical characters: PR.XX

[redacted]

3.1. Creation and identification of documents

All documents are identified by name, code, date of version, version number and copy number.

[redacted]

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

Commented [AS91008]: Records are coded with five alphanumerical characters: PR.XX.Y

[redacted]

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] [job title]

Commented [AS91009]: In case there are several document levels, for example policies - procedures - instructions, which must be approved by different management levels, such requirements should all be specified.

[redacted]

for suitability and adequacy. Documents are approved in the following way: [job title] will approve the paper documents by signature.

Commented [AS910010]: 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 [AS910011]: Where different authorized persons or approval methods exist for different relevant documents all must be identified.

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 [job title] distributes the numbered copy to the place of use. Persons named in the distribution list verify receipt of the document.

Commented [AS910012]: If using electronic documents you [illegible]

The Quality Policy is the only document available to the public. The rest of the documents can be delivered to external parties only with written approval of [job title], and they are labeled as "Uncontrolled copy," which guarantees the adequacy of the document only at the moment of issuance.

3.4. Withdrawal of outdated documents

The new version of a document is immediately distributed to the place of use upon creation and approval (as explained in the previous clause) accompanied with withdrawal of the outdated document. After replacing, the outdated document is destroyed or labeled "Replaced by version no. __" if it is intended to be archived as a reference or for any other purpose.

Commented [AS910013]: If using electronic documents, write something like this "If there is an older version of the document, [job title] must delete it from the valid documents folder and move it to [folder name]".

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

Persons named on the distribution list verify the receipt of a new version of the document, and [job title] verifies the receiving of the outdated document.

Commented [AS910014]: Delete if you use electronic documents.

3.5. Document updates and changes

The person listed as document owner has the responsibility for updating and changing the document. Updates and review are performed in line with the frequency defined in the List of Internal Documents.

All changes to the document must be made using "Track changes," making visible only the revisions to the previous version, and must be briefly described in the "Change History" table; if the Track changes option is unavailable, or if the changes are too numerous, then the Track changes option is not used.

Each document should preferably have a "Change History" table used to record every change made to the document.

3.6. Documents of external origin

Each external document that is necessary for the planning and operation of the QMS must be recorded in the Incoming mail register. The incoming mail register must contain the following information: (1) document number, (2) sender, (3) document name, (4) date of receipt, and (5) name of the person to whom the document has been forwarded.

Commented [AS910015]: Adapt the document name to the organization's existing record maintenance system.

Commented [AS910016]: Add additional information if required by the organization's record maintenance system.

The person who receives mail and courier parcels must forward them to [job title], who must make a record in the incoming mail register. The person who receives electronic mail must forward such a document to [job title], who must also record it in the incoming mail register.

3.7. Records control

3.7.1. Record managing and labeling

Each internal document in the QMS must define how records resulting from the use of such a document should be managed – i.e., it must specify the following: (1) record name, (2) storage location, (3) person responsible for storage, (4) controls for record protection, and (5) retention time.

Reports and analysis that are conducted periodically can be in free form, but they must include the following: name/subject of report (analysis), creation date, and signature of the person who conducted the analysis.

Records that arise from legal or regulatory requirements or from IT systems are accepted in defined form and they are not subjected to marking described in this procedure.

While records are in use, the person responsible for maintaining the record guarantees exactness of entered data, and prevents unauthorized entry, changes and destruction of such record.

3.7.2. Record availability and retrieval

Employees of the organization may access stored records only after obtaining permission from the person designated as the person responsible for storing individual records. If the sensitivity of certain records is such that permission for access must be obtained from a different person, this must be stated in the concerned internal document in the chapter describing records control.

Access and retrieval rights for records are determined by the owner of individual records. [job title] is responsible for destroying all records of which the retention time has expired.

If the records are stored on computer they must be backed up at least [describe the usual practice in organization].

3.7.3. Record archiving and destroying

Records with expired retention times are destroyed in a way that prevents their further use and the data of destruction is entered into Registry of Records for Detention/Central Archive.

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	

Commented [AS910017]: If you want to find out more about record control, see this blog from 9001Academt: Some tips to make Control of Records more useful for your QMS http://advisera.com/9001academy/blog/2014/01/28/tips-make-control-records-useful-qms/

Commented [AS910018]: More details should be provided if records are stored on various media.

Commented [AS910019]: E.g. once a day.

Commented [AS910021]: Adapt the information in this column to the normal practice in your company.

Commented [AS910020]: Adapt the information in this column to the normal practice in your company.

List of Internal Documents	PR.00.1	Older versions are archived for 3 years	[office of [job title]]	Records are stored in file cabinet [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 [describe name/location]	[job title]
List of Types of Records	PR.00.3	Older versions are archived for 3 years	[office of [job title]]	Records are stored in file cabinet [describe name/location]	[job title]
Registry of Records for Detention/Central Archive	PR.00.4	Older versions are archived for 3 years	[office of [job title]]	Records are stored in file cabinet [describe name/location]	[job title]
Incoming mail register (electronic form – Excel spreadsheet)		3 years	[in the computer of owner of document]	Only [job title] has the right to make entries into and changes to the incoming mail register.	[job title]

Commented [AS910022]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [AS910023]: Adapt to the organization's standard practice.

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

5. 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 Detention/Central Archive