PROCEDURE FOR DOCUMENT AND RECORD CONTROL

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

Distribution list

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<th>Copy No.</th>
<th>Distributed to</th>
<th>Date</th>
<th>Signature</th>
<th>Returned Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Comment [9A1]: All fields in this document marked by square brackets [ ] must be filled in.

Comment [9A2]: Adapt to the existing practice in organization.

Comment [9A3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Created by</th>
<th>Description of change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1</td>
<td>9001Academy</td>
<td>Basic document outline</td>
</tr>
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</table>

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1. Purpose, scope and users

The purpose of this procedure is to ensure control over creation, approval, distribution, usage and updates 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 form – 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].

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

2. Reference documents

- ISO 9001:2008, clauses 4.2.3; 4.2.4
- Quality Manual
- [other documents and regulations specifying document control]

3. Control of documents

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

3.1. Creation and identification of documents

All documents are identified by name, code, date of version, version number and copy number. Identification of documents is performed as follows:

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

3.2. Document approval

All documents, regardless of whether they are new documents or new versions of existing documents, record templates and working instructions must be approved by [job title]. Documents are approved in the following way: [job title] will approve the paper documents by signature.

3.3. Publishing and distributing documents
After approving a draft or a new version of a document, [job title] keeps the original version and [job title] also creates the updated version in the database for both receipt of the document.

The Quality Policy is the only document available to the public. The rest of the documents can be downloaded to internal 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 withdrawal of the previous version. The version number in the title is inserted with an arrow. The document is labeled “Replaced by version no.” if it is intended to be archived as a reference.

[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.

3.5. Document updates

The person listed as an owner has the responsibility for updating the document 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 in 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) date of receipt, (4) date of receipt, and (5) name of the person to whom the document has been forwarded.

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 documents 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

Comment [9A9]: If using electronic documents you can write something like this: “[job title] must publish the users of the document by e-mail.”

Comment [9A10]: 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].”

Comment [9A11]: Delete if you use electronic documents.

Comment [9A12]: Adapt the document name to the organization’s existing record maintenance system.

Comment [9A13]:
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) and (4) 

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

Records that arise from


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 required retention times are destroyed in a way that prevents their further
use and the date of destruction is entered into List of Documents for Detention/Archive.

4. Managing records kept on the basis of this document

<table>
<thead>
<tr>
<th>Record name</th>
<th>Code</th>
<th>Storage</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Internal</td>
<td>PR.01.1</td>
<td>Older versions are archived for 3 years</td>
<td>[job title]</td>
</tr>
<tr>
<td>documents</td>
<td></td>
<td>Location: [office of Management Representative]</td>
<td>Records are stored in file cabinet [describe name/location]</td>
</tr>
<tr>
<td>List of External</td>
<td>PR.01.2</td>
<td>Older versions: [office of Management Representative]</td>
<td>Records are stored in file</td>
</tr>
</tbody>
</table>

Comment [9A14]: More details should be provided if records are stored on various media.

Comment [9A15]: E.g., once a day.

Comment [9A17]: Adapt the information in this column to the normal practice in your company.

Comment [9A16]: Adapt the information in this column to the normal practice in your company.

Comment [9A18]: If the record is in electronic form, write the name of the folder on Management Representative's computer.
### Documents

<table>
<thead>
<tr>
<th>Documents</th>
<th>are archived for 3 years</th>
<th>Representative</th>
<th>cabinet [describe name/location]</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Type of Records</td>
<td>PR.01.3</td>
<td>Older versions are archived for 3 years</td>
<td>[office of Management Representative]</td>
</tr>
</tbody>
</table>

| List of Records for Detention/Central Archive | PR.01.4 | Older versions are archived for 3 years | [office of Management Representative] | Records are stored in file cabinet [describe name/location] |

| 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. |

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