ISO 9001:2015

Control of Documented Information

This procedure is the property of Your Company. It must not be reproduced in whole or in part or otherwise disclosed without prior written consent.

The official controlled copy of this quality manual is the digitally signed PDF document held within our network server and visible to all authorised users. All printed copies, and all electronic copies and versions, except the ones described above, are considered uncontrolled copies which should be used for reference only.
# Contents

1 Control of Documented Information .......................................................... 3
  1.1 Introduction & Purpose ............................................................................. 3
    1.1.1 Process Activity Map ................................................................. 3
    1.1.2 References ................................................................................. 3
    1.1.3 Terms & Definitions ................................................................... 3
  1.2 Application & Scope ............................................................................... 4
  1.3 Requirements ....................................................................................... 4
  1.4 Creating, Updating & Controlling Documented Information .............. 4
    1.4.1 General ....................................................................................... 4
    1.4.2 Document & Data Identification, Approval and Use ................... 5
    1.4.3 Revising a Controlled Document .............................................. 5
    1.4.4 External Documents .................................................................. 5
    1.4.5 Uncontrolled Documents ......................................................... 5
    1.4.6 Document Change Requests ..................................................... 6
    1.4.7 International Standards & Specifications .................................. 6
    1.4.8 Obsolete Documents .................................................................. 6
  1.5 Management System Records .............................................................. 6
    1.5.1 Protection, Storage and Retrieval of Documented Information .... 6
    1.5.2 Retention Period for Records ..................................................... 7
    1.5.3 Disposal of Records .................................................................. 7
    1.5.4 Register of Documented Information ........................................ 7
  1.6 Organizational Knowledge ................................................................. 8
    1.6.1 General ....................................................................................... 8
    1.6.2 Sources of Organization Knowledge ......................................... 8
  1.7 Forms & Records .................................................................................. 9
1 Control of Documented Information

1.1 Introduction & Purpose

The purpose of this procedure is to ensure that all relevant documented information and organizational knowledge which forms an integral part of our quality management system is managed under controlled conditions and that all documented information is reviewed and approved by authorized personnel prior to issue.

1.1.1 Process Activity Map

With what

- Retained information
- Maintained information

Activity

- Controlling documented information and organizational knowledge

Output

- Document approval
- Process control
- Continual improvement
- Document changes
- Record control

With what measure

- No. of incorrect documents
- No. of document errors
- No. of document changes

Input

- Revised QMS documents
- Standards
- Customer drawings
- Specifications
- Process changes

How

- Documented information register
- Disaster recovery

With who

- Document Control
- Quality Manager

1.1.2 References

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS EN ISO 9000:2015</td>
<td>Quality management systems</td>
<td>Fundamentals and vocabulary</td>
</tr>
<tr>
<td>BS EN ISO 9001:2015</td>
<td>Quality management systems</td>
<td>Requirements</td>
</tr>
<tr>
<td>BS EN ISO 9004:2000</td>
<td>Quality management systems</td>
<td>Guidelines for performance improvements</td>
</tr>
<tr>
<td>BS EN ISO 19011:2011</td>
<td>Auditing management systems</td>
<td>Guidelines for auditing</td>
</tr>
</tbody>
</table>

1.1.3 Terms & Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>ISO 9000:2015 Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented Information</td>
<td>Information (3.8.2) Required to be Controlled and Maintained</td>
</tr>
<tr>
<td>Record</td>
<td>Document (3.8.5) Stating Results Achieved or Providing Evidence</td>
</tr>
<tr>
<td>Quality Manual</td>
<td>Specification (3.8.7) for the Quality Management System</td>
</tr>
<tr>
<td>Specification</td>
<td>Document (3.8.5) Stating Requirements</td>
</tr>
<tr>
<td>Objective Evidence</td>
<td>Data (3.8.1) Supporting The Existence or Verity of Something</td>
</tr>
</tbody>
</table>
1.2 Application & Scope

Documented information is retained to provide evidence of conformity to the requirements specified by ISO standards, customer requirements and of the effective operation of our management system. Your Organization uses standard forms and templates accessed via a local area network computer system. This documented procedure defines the controls for:

1. Approving documents for adequacy prior to issue;
2. Reviewing and revising as necessary and re-approving documents;
3. Ensuring that changes and current revision status of documents are identified;
4. Ensuring that relevant versions of applicable documents are available at points of use;
5. Ensuring that documents remain legible and readily identifiable;
6. Ensuring that documents of external origin are identified and their distribution controlled;
7. Preventing the unintended use of obsolete documents;
8. Ensuring that documents of external origin are identified and their distribution controlled.

This procedure applies to all quality management system documentation and is to be followed by all personnel where appropriate.

1.3 Requirements

Top management ensures that when we create documented information it is appropriately identified and described (e.g. title, date, author, reference number) and is available in an appropriate format (e.g. language, software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy.

An electronic document management system, which is backed up and updated as required, is used to retain documented information ensuring only the current versions are available to users. Records from process outputs are generated and maintained by the departments responsible for their creation. For electronic records, back up procedures are established, employees are responsible for backing up their data.

1.4 Creating, Updating & Controlling Documented Information

Your Organization applies the following criteria to all types of ‘documented information’ in order to assess whether the information is necessary for demonstrating the effectiveness of our QMS, and whether it should be formally controlled.

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.

1.4.1 General

All documents and data are reviewed and approved by authorized personnel prior to issue. Each department issues and maintains its own documents. Current revisions of appropriate documents are available at locations where they are used. Documents controlled by this procedure include but are not limited to the following: