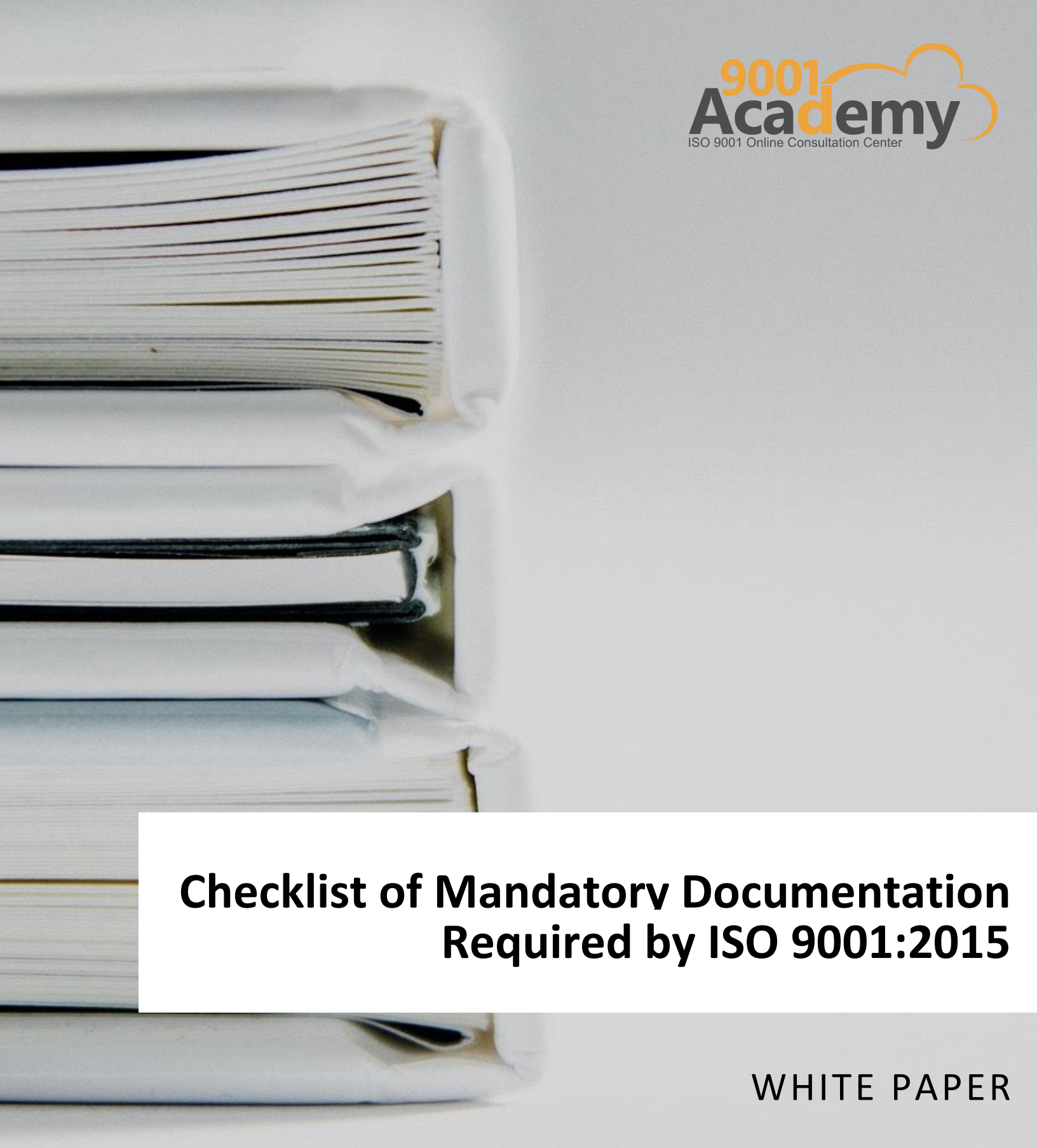

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Checklist of Mandatory Documentation Required by ISO 9001:2015

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BASIC OVERVIEW

It is easy to become overwhelmed with documentation in the belief that every single process that is in place in an organization must be documented, without realizing that this is not necessary to meet the requirements of the ISO 9001 standard. The 2015 revision of the standard become more liberal regarding documentation requirements, meaning that there are no longer six mandatory procedures as in the previous 2008 version of the standard. ISO 9001 also identifies many records that need to be maintained, which are generated by the processes of the Quality Management System. Below is discussed which documents and records are mandatory, and which are optional.

1. Which documents and records are required?

Mandatory Documents	ISO 9001:2015 Clause
Scope of the Quality Management System	4.3
Quality Policy	5.2
Quality Objectives and Plans for Achieving Them	6.2

Mandatory Records	ISO 9001:2015 Clause
Record of Maintenance and Calibration of Monitoring and Measuring Equipment	7.1.5.1
Competence Records	7.2
Product/Service Requirements Review Record	8.2.3.2
Record of New Requirements for Product or Service	8.2.3.2
Design and Development Inputs Record	8.3.3

Record of Design and Development Controls	8.3.4
Design and Development Outputs Record	8.3.5
Record of Design and Development Changes	8.3.6
Record of Evaluation of External Provider (supplier)	8.4.1
Record of Product/Service Characteristics	8.5.1
Record of Changes on Customer's Property	8.5.3
Record of Changes in Production/Service Provision	8.5.6
Evidence of Product/Service Conformity	8.6
Record of Nonconformity	8.7.2, 10.2.2
Monitoring Performance Information	9.1.1
Internal Audit Program and Results	9.2.2
Management Review Results	9.3
Nonconformities and Corrective Action	10.2.2

These are the documents and records that are required to be maintained for the ISO 9001 Quality Management System, but you should also maintain any other records that you have identified as necessary to ensure your management system can function, be maintained, and improve over time.

2. Commonly used non-mandatory documents

Non-Mandatory Procedures	ISO 9001 Clause
Determining Context of the Organization and Interested Parties	4.1, 4.2
Procedure for Addressing Risks and Opportunities	6.1.
Competence, Training and Awareness Procedure	7.2, 7.3
Procedure for Control of Documents and Records	7.5
Sales Procedure	8.2
Procedure for Design and Development	8.3
Procedure for Control of Externally Provided Processes, Products and Services (outsourced processes)	8.4.1
Procedure for Production and Service Provision	8.5
Warehousing Procedure	8.5.4
Procedure for Measuring Customer Satisfaction	9.1.2
Procedure for Internal Audit	9.2
Procedure for Management Review	9.3
Procedure for Nonconformity and Corrective Action	10.2

While ISO 9001 does not require that you document all of the procedures, there are several processes that are mandatory to be established in order to generate the required records that are outlined in the first section. Remember these processes and procedures are not required to be documented; however, many companies choose to do so. One rule of thumb when deciding if you want to document a process is this: if there is a chance that the process won't be carried out as planned, then you should document it. In many cases this is the best way to ensure that your Quality Management System is reliably implemented.

3. How to structure documents and records

Determining Context of the Organization and Interested Parties

This is a new requirement of the standard that can bring some ambiguities, and it is a good idea to document the process of determining the context and identifying interested parties and their expectations, since it is being done for the first time. This document should contain all internal and external issues to be considered, as well as the process and responsibilities for identification of interested parties and their needs and expectations. Procedure for Determining Context of the Organization and Interested Parties can be of great help in implementation of these new requirements.

For more information, see: How to identify the context of the organization in ISO 9001:2015.

QMS Scope

This document is usually rather short, and written at the beginning of the ISO 9001 implementation. Its purpose is to define the boundaries of the QMS and to determine to which parts of the organization the QMS applies. Normally, it is a standalone document called Scope of the QMS, although it can be merged into a Quality Manual.

Quality Policy

The Quality Policy is intended to be a company's documented intention to comply with appropriate requirements, increase customer satisfaction, and continually improve. The policy is the focus for the company to work toward and should readily convey the goal of the organization. It is a standalone document, but is often documented in a Quality Manual and sometimes posted throughout the organization as a way of communicating to all employees, since it is important that every employee understand how the policy relates to his or her job. For more information, see How to Write a Good Quality Policy.

Risks and Opportunities that need to be addressed

This is a new requirement that introduces significant changes to the QMS. According to the new version, the risks and opportunities regarding the QMS must be identified and addressed, but there is no requirement to use any methodology or write a procedure. The process of addressing risks and opportunities includes consideration of internal and external issues relevant to the QMS, interested parties, and scope of the QMS. Considering the importance of this new requirement and the fact that it

introduces a completely new process into the organization, it is recommended that it be documented in the form of a procedure.

For more information, read: Risk-based thinking replacing preventive action in ISO 9001:2015 – The benefits and Methodology for ISO 9001 Risk Analysis.

Quality Objectives and Plans for Achieving Them

The requirements regarding setting the quality objectives remained as they were in the previous version of the standard; they still need to be measurable and timed. However, the standard now requires plans for achieving the objectives, meaning that the organization will have to assign responsibilities and dedicate resources for achieving the objectives. These requirements can be met in separate documents, but it is much easier to create a Quality Objectives document and fulfill all the above-mentioned requirements.

For more information, see: How to Write Good Quality Objectives.

Competence, Training and Awareness records

Introducing quality management into an organization often requires additional training of relevant employees. Describing the process of managing human resources by documenting a procedure that defines identification of training needs, training planning, conducting and evaluation of training effectiveness, as well as assigning responsibilities for this, is the best way to ensure that the requirements are met. Although it is not a requirement of the standard, good practice shows that the Procedure for Competence, Training and Awareness can be of great help to an organization. The standard explicitly requires only the evidence of competence, and that is the Training Record.

See also: How to ensure competence and awareness in ISO 9001:2015.

Procedure for Control of Documents and Records

Managing documented information is defined by many requirements within clause 7.5 in the standard. Activities of approval, update, managing changes, and ensuring that the relevant version of the document is in use are best to be defined in a documented procedure.

The company must also define rules to maintain its records that show the QMS is implemented and maintained, including how they identify, store, and protect the records so that they can be retrieved as necessary, for the correct amount of time, and destroyed when no longer needed but not before. If you need more information, see New approach to document and record control in ISO 9001:2015.

Sales procedure

Although it is not a mandatory procedure, the standard prescribes numerous rules regarding communication with customers, determining requirements related to product and services, and activities regarding review of these requirements. Good practice shows that the best way to conform to all these requirements is to document them, together with responsibilities. The only mandatory documented information here are the records of reviewing requirements related to product and service, as well as information about new requirements for products and services.

Procedure for Design and Development

Requirements regarding the design and development process are among the most demanding in the standard. Every step of the design and development process needs to be documented in the form of a record, from design and development inputs, controls, and outputs, to changes in design and development. Considering all the requirements regarding the design and development process, it is best to document the Procedure for Design and Development and define all mandatory records that should accompany the procedure.

For more information, see: ISO 9001 Design Verification vs. Design Validation.

Procedure for control of externally provided processes, products and services (outsourced processes)

Creators of the standard decided to use this rather robust formulation of something that is basically the Procedure for Purchasing and Evaluation of Suppliers. Although the purchasing process doesn't have to be documented, the standard requires companies to establish control over its externally provided processes, products, and services. The standard does require the criteria for evaluation, selection, monitoring, and re-evaluation of the suppliers to be documented, and the best way to do it is through the procedure.

For more information, see: Purchasing in QMS – The Process & the Information Needed to Make it Work.

Procedure for production and service provision

The standard requires production and service provision processes to be under control in terms of availability of necessary documented information about product or service characteristics, intended results, availability of needed resources, monitoring and measurement activities, etc. This rather complex process will hardly achieve the intended outcomes without clearly defined rules documented in the Procedure for Production and Service Provision.

See also: Understanding Product & Service Provision in ISO 9001.

Warehousing procedure

The importance and necessity of this procedure will vary depending on the type of business the company performs, but the requirement for product preservation is one of the most crucial ones in the way of the product or service toward the end user. In cases when the storage conditions can have great influence on the product quality, rules for preservation of the product during storage should be documented in the Warehousing Procedure.

Monitoring performance information

The new version of the standard emphasizes the importance of measuring and evaluation of QMS performance. The organization needs to determine what should be monitored, how, and when. This doesn't have to be in one document, meaning that necessary monitoring and measuring is usually included in related process procedures. But, it is good to have an overview of key performance indicators and their status in the form of a Matrix of Key Performance Indicators.

Learn more here: Analysis of measuring and monitoring requirements in ISO 9001:2015.

Internal audit

How do you audit your Quality Management System to make sure that it is performing as planned and is effective? Who is responsible for planning and carrying out the audits? How do you report the results, and what records are kept? How do you follow up on corrective actions noted in audits? Learn more in this article about the Five Main Steps in ISO 9001 Internal Audit. You must also keep records of these activities to show QMS conformance and improvement.

See also this short handbook containing expert guidance on internal audit: ISO Internal Audit: A Plain English Guide.

Management review

Management review as a process hasn't suffered any changes in the new ISO 9001:2015 revision in terms of how and how often it should be conducted. However, the mandatory inputs and outputs of the management review have changed. It is now required for the top management to review internal and external issues relevant to the QMS, as well as the effectiveness of actions taken to address risks and opportunities. As a result of the management review, there should be decisions regarding opportunities for improvement of the QMS, need for changes of the system, and resources needed. The best way to keep track of what needs to be reviewed and the expected results of the management review is to document the Procedure for Management Review.

For more information, see: How to make Management Review more useful in the QMS.

Nonconformity and corrective action

What actions are in place, and who is responsible for making sure that a nonconformity is addressed? How do you ensure that corrections are made, and what records are kept of the process? Find out more here: Understanding dispositions for ISO 9001 nonconforming product. How do you review nonconformities, determine causes, and evaluate the need for actions to correct them? How do you implement the necessary actions, review that the actions were effective, and keep records of the actions taken? With the Quality Management System you will find that you have non-conformances occur within your processes that you will need to correct; and when you investigate the root cause of these problems, you will have corrective actions taken. You will also need to keep records of these activities to show improvement. Learn how to do this with Seven Steps for Corrective and Preventive Actions to support Continual Improvement.

4. Sample Documentation Templates

Here you can download a free preview of the ISO 9001 Documentation Toolkit – in this free preview you will be able to see the Table of Contents of each of the mentioned documented procedures, as well as a few sections from each document.

Useful resources

These online materials will help you with ISO 9001:2015 implementation:

- ISO 9001 Foundations Course – free online training that explains the basics of the standard, and the implementation steps.
- Webinars – if you are not sure where to begin or how to comply with ISO 9001, registering for some of our webinars could be a good starting point.

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