

# **Audit-Checklist<sup>©</sup> for ISO 9001:2015**

(based on edition ISO 9001:2015)

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## 0. Introduction

On the occasion of the complete revision of the Standard ISO 9001 the Audit-Checklist (edition 2008) has been entirely revised and adapted to the new structure for management systems standards.

The new requirements, detailed definitions or changes in ISO 9001:2015 compared to ISO 9001:2008 have been incorporated and the main alterations/changes are highlighted in red.

Organizations living a mature management system will discover in some items that they already fulfil - at least partially - the changed requirements. A thorough reconciliation however is compulsory required to ensure the fulfilment of the normative complementary requirements.

Thus, the checklist serves also as means for the review of the existing management systems with regard to necessary modifications due to the revision of the Standard.

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## 1. Objectives and purposes of this checklist

This checklist was made for everyone who is engaged in the implementation and realization of the Standard ISO 9001:2015. As work instrument and signpost it supports the development of a new management system as well as its implementation.

With a consistent realization of all questions in the checklist the requirements of the Standard ISO 9001:2015 will be fulfilled.

<b>For what</b>	<ul style="list-style-type: none"><li>• Analysis of the present state and definition of actions to implement the Standard ISO 9001:2015</li><li>• Performance of internal audits</li></ul>
<b>For whom</b>	<ul style="list-style-type: none"><li>• Quality managers</li><li>• Internal auditors</li><li>• Process owners</li></ul>
<b>Which requirements</b>	<ul style="list-style-type: none"><li>• Basic knowledge of the Standard ISO 9001:2015</li><li>• Training as auditor (recommended)</li></ul>
<b>Advantage and benefits</b>	<ul style="list-style-type: none"><li>• A checklist, matched with the Standard</li><li>• Structured procedure</li><li>• Efficient analysis of the present state</li><li>• Analysis of strengths and weaknesses</li><li>• Quick overall picture</li><li>• Quick overview of the action catalogue</li><li>• Can be adapted to own needs (add, leave out)</li><li>• Time savings and thus cost savings analysing the changes based on the revision of the Standard</li></ul>
<b>Delivery agreement</b>	<p>This Audit-Checklist® may be saved and adapted electronically by the enlisted user. It is not allowed to pass it on to a third party, even within the company. Should the Audit-Checklist® be used in different parts of the company, a multi user agreement must be reached with the author of the Audit-Checklist®.</p>
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## **2. INFORMATION FOR THE USER**

### **2.1 FUNDAMENTAL DEFINITIONS**

- The term "quality" has been omitted wherever possible (except for official titles) to provide the organization with the possibility of broader considerations for the fulfilment of requirements.
- There should be no favouritism of interests by the use of limiting terms like "quality", "security" or "environment".
- The term "quality management system" is replaced just by "management system" to indicate the overall validity of the comprehensive management system of the organization.

### **2.2 STRUCTURE**

- The numbers and the names of the passages correspond to those of ISO 9001:2015.

### **2.3 PRESENTATION**

- For complementary clarification, some sections have introductory "general notes" which are presented in bold letters size 8.
- Explaining or specifying parts of questions are presented in italic letters and in size 7, to form the question itself clearer.
- Page break is defined by the relevant printer configuration and has always to be checked

### **2.4 REFERENCING**

- Requirements of the standard can be recognised by the question number and the corresponding reference (i.e.: 3 (4.2)) to ISO 9001.
- Additional questions can be recognised by the question number and the term "addition" (i.e.: 6 (add.))

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## 2.5 FORMULATION

- Questions referencing to the standard are related only to the requirements of the standard and are to be understood as minimal claim.
- Additional questions include descriptive requirements which in this way are not demanded by ISO 9001:2015.
- Additional questions enable the organisation to get orientated by well-known or proven practice.
- Additional questions enable recognition of the entrepreneurial aspect in the management system.

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(structure according to ISO 9001:2015)

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Audited unit / persons:

No.	Questions regarding the MS	Description Process manual	A*)	Application / deployment	A*)
<b>4</b>	<b>CONTEXT OF THE ORGANIZATION</b>				
<b>4.1</b>	<b>UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT</b>				
	<p>General notes:</p> <ul style="list-style-type: none"> <li>Context of the organization: business environment, combination of internal and external issues which may have an impact on the approach of an organization regarding the development and the achievement of its objectives.</li> <li>Issues can include positive and negative factors or conditions for consideration.</li> <li>Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.</li> <li>Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.</li> <li>Intended results of QMS: Ability of an organization to continually fulfil <ul style="list-style-type: none"> <li>Customer needs as well as for provided products and services relevant legal requirements</li> <li>its own requirements</li> <li>its objective to enhance customer satisfaction.</li> </ul> </li> </ul>				
1 (4.1)	<p><b>Are external and internal issues determined, which are relevant for the purpose and the strategic direction of the organization and that affect its ability, to achieve the intended results of its management system?</b></p> <p>(e.g. list of internal/external issues, trends influencing the organization and resulting opportunities + risks, environmental analysis, strength-/opportunities analysis, PESTEL-Analysis, SWOT-Analysis etc.)</p>				
2 (4.1)	<p><b>Does the organization monitor and review information about these external and internal issues?</b></p>				

Date:		Signature	
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<b>Remarks:</b>		
* Assessment: 0= not applicable	1=fulfilled	2= not fulfilled