

# **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.

**For what**

- Analysis of the present state and definition of actions to implement the Standard ISO 9001:2015
- Performance of internal audits

**For whom**

- Quality managers
- Internal auditors
- Process owners

**Which requirements**

- Basic knowledge of the Standard ISO 9001:2015
- Training as auditor (recommended)

**Advantage and benefits**

- A checklist, matched with the Standard
- Structured procedure
- Efficient analysis of the present state
- Analysis of strengths and weaknesses
- Quick overall picture
- Quick overview of the action catalogue
- Can be adapted to own needs (add, leave out)
- Time savings and thus cost savings analysing the changes based on the revision of the Standard

**Delivery agreement**

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®.

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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.))