ISO 9001:2015 Documentation Toolkit updates

Version 2.0, 2015-09-01

General updates

Documents that are changed	Description of the changes
Most of the documents in the toolkit.	In the section 2 Reference documents, new clause numbers are added to correspond with the new version of the standard, along with new documents and records. In comments, references to articles are added, which explain how the particular activity is to be done according to ISO 9001:2015. Since the management representative no longer exists as a function in the standard, it is excluded from all procedures.

Document-specific updates

Documents that are changed	Description of the changes
Procedure for Document and Record Control	Section 3.1 – rule for formatting the documents is added. Section 3.2 – reviewing for suitability and adequacy of documents before approval is added. Section 3.3 is renamed to comply with the new terms of the 2015 revision. Section 3.5 is renamed and covers both updating and changing the documents.
Quality Policy	Additional statements regarding the context of the organization and environmental protection.
Quality Manual	The manual is completely rewritten, the clauses in the document are aligned with new clauses of the standard, and new requirements are included.
Procedure for Determining the Context of the Organization and Interested Parties	This is a new procedure that describes the process of determination of the context of the organization and interested parties, and sublimates the process of identification and evaluation of compliance obligations, former legal and other requirements. New records are amended to this procedure.
Appendix 1 – List of Interested Parties	This new record, List of Interested Parties, is used for collecting information about relevant interested parties and amended to the Procedure for Determining the Context of the Organization and Interested Parties.
Appendix 2 – Conformance Evaluation Record	This new record is used for monitoring conformance with needs and expectations of interested parties.

Scope of Quality Management System	Completely new document that defines the boundaries of the Quality Management System.
Procedure for Competence, Training and Awareness	The old Procedure for Human Resources was renamed. Section 3.1 is updated in order to comply with the requirement to provide necessary competence, training, and awareness for the effective implementation of the QMS and operation and control of the organization's processes. Section 3.2 – additional criteria for determining training needs is added in order to comply with the new requirements. Section 3.3 is renamed and supplemented to comply with requirements for awareness. Section 3.6 is supplemented to exclude awareness trainings from training effectiveness assessment.
Procedure for Addressing Risks and Opportunities	The purpose of this new procedure is to help the organization to adapt and apply risk-based thinking. It also refers to one new record: Registry of Key Risks and Opportunities.
Appendix 1 – Registry of Key Risks and Opportunities	This new record is used for listing all key risks and opportunities, together with plans for addressing them.
Sales Procedure	Section 3.2 is supplemented to cover both products and services to be sold. Section 3.3 is updated to comply with the new requirements; additional rules for receiving and accepting customer requests are added. Section 3.4.1 – additional rules are added regarding acceptance of changes in customer requirements. Section 3.4.2 – reference to Customer Requirement Review Checklist is added.
Appendix 1 – Customer Requirement Review Checklist	Instead of the term "Legal," the term "Statutory and regulatory" is used in order to comply with the terminology of the standard.

Procedure for Design and Development	Section 3.3 is completely new, added to comply with requirements regarding design and development planning. Section 3.4 is renamed, and a new rule is added in order to align with new requirements. Section 3.4.1 is renamed to comply with the terminology of the standard. Section 3.4.2 is renamed to comply with the terminology of the standard. Section 3.4.4 is supplemented with new rules regarding internal and external resource needs for design and development of products and services, requirements for subsequent provision of products and services, and potential consequences of failure due to the nature of products and services. Section 3.6 is updated in order to be compliant with the new terminology. Section 3.7 is completely new and refers to design and development controls. Section 3.8 is supplemented with new rules to comply with the new requirements.
Appendix 1 – Project Task	New record inputs are added to the record.
Appendix 4 – Design Review Minutes	The record is now aligned with the new terminology of the standard.
Procedure for Purchasing and Evaluation of Suppliers	The scope of the procedure is updated to comply with the new terminology. Section 4 is supplemented with rules for establishing controls for externally provided resources. Section 4.1 has additional rules for defining needs for purchase. Section 4.2 is updated with new criteria for evaluating offers from suppliers. Section 4.4 is renamed in order to comply with the new terminology, and responsibilities are defined in more detail now.
Procedure for Production and Service Provision	Section 3.3.4 – new terms are introduced to comply with the new terminology. Section 3.3.5 – the requirement to ensure the availability of monitoring and measurement resources is supplemented to this section. Section 3.3.6 is a completely new section added to address new requirements. Section 3.3.7 is renamed and new rules regarding product release and post-delivery services are added to align with the new requirements.
Appendix 3 – Quality Plan	New sections are added to address the new requirements.
Appendix 6 – Production/Service Changes Review Record	New record that addresses the requirements for reviewing changes in production or service provision.

Procedure for Management of Nonconformities and Corrective Actions	The procedure is renamed, preventive actions are excluded from the procedure, it is merged with the Procedure for Control of Non-Conforming Product, and an additional step is included in implementation of corrective actions.
Appendix 1 – Nonconformity Record	The old record is renamed and the new one covers not only the nonconforming product, but also any nonconformity that may occur.
Appendix 2 – Corrective Action Record	The appendix is renamed and preventive actions are no longer part of the appendix.
Appendix 3 – Registry and Status of Corrective Actions and Nonconformities	The appendix is renamed and preventive actions are no longer part of the appendix.
Procedure for Equipment Maintenance and Measuring Equipment	Section 3.3.1 is supplemented with an additional rule for calibration to comply with the new requirements.
Appendix 2 - Plan for Preventive Maintenance of Equipment	An additional column is introduced to facilitate the traceability of equipment maintenance.
Procedure for Measuring and Monitoring Customer Satisfaction	Section 3.7 is updated to clarify the way amending records are used.
Procedure for Internal Audit	The purpose of the procedure is further clarified, and also preventive actions are excluded from the procedure.
Appendix 1 – Internal Audit Checklist	A completely new Internal Audit Checklist is created to address requirements of the new version of the standard.
Procedure for Management Review	New requirements regarding input and output elements of management review are added.
Appendix 3 – Management Review Minutes	The record is changed to comply with new requirements of the standard, and new input elements for management review are added.