Twelve-step transition process using ISO 9001:2015 Transition Toolkit

9001 Academy
ISO 9001 Online Consultation Center

WHITE PAPER

June 22, 2016

1. Purpose

This white paper is intended for users of the ISO 9001 Transition Toolkit, to help the organization make necessary changes in their QMS documentation and processes.

2. Other useful resources

For more information about the ISO 9001:2015 revision, see these articles:

Infographic: ISO 9001:2015 vs. 2008 revision – What has changed?

How to ensure competence and awareness in ISO 9001:2015

What will be the destiny of the management representative in the new ISO 9001:2015?

How to prepare your company for the ISO 9001 certification audit

ISO 9001:2015 vs. ISO 9001:2008 matrix

ISO 9001:2015 Foundations Course

3. Timing of the transition

The ISO 9001:2015 standard was published on September 22, 2015. Organizations are granted a three-year transition period from that date to comply with the current version of the standard, at which time the 2008 version and any certification pertaining to it will become obsolete. This means that you may have surveillance audits against the 2008 revision until September 22, 2018, although some certification bodies have announced that they will stop issuing new certificates against the 2008 revision by September 2016, so it is advised that you consult your own certification body regarding your organization's circumstances if you are pursuing your initial 9001 accreditation.

4. Twelve-step transition process

The easiest way to make the upgrade to the 2015 revision is by following these steps:

Before you start

The transition is not only about implementing new requirements, but also about revising the entire system, and it is a great opportunity for improvement. So, just before starting, the people involved in the transition project must first get familiar with the standard and its new requirements in order to assess the existing system and find out what additional changes must be made in order to achieve full compliance with ISO 9001:2015. For that reason, we added to the toolkit the Internal Audit Checklist that contains all requirements of ISO 9001:2015 in the form of "yes or no" questions. Every question with a negative answer will require additional actions that must be included in the transition project.

1) Define the context of the organization

Clause 4 of the 2015 revision is a new requirement that requires defining the context of the organization. This is a critical change, as this consideration will form the basis for your whole Quality Management System (QMS). Organizations must now consider all items that may influence the QMS performance, including external, internal, cultural, social, economic, technological, and legal factors. These are considered to be factors that will influence the organization's objectives, purpose, and sustainability. It is advised that the consideration and outcome of this process be demonstrated within your Quality Policy, or equivalent document.

To define context of the organization, ISO 9001 does not require the organization to develop a procedure or any other document. However, since this is a completely new concept for ISO 9001 and the Quality Management System, it is recommended to create a procedure to define what aspects of the organization must be considered in order to determine context of the organization.

In folder 01 Determining context of the organization, you will find the Procedure for Determining Context of the Organization and Interested Parties, with comments that will help you to fill it in.

Read more here: How to identify the context of the organization in ISO 9001:2015.

2) List all interested parties

This also belongs to clause 4, but is also new to the 2015 revision. The 2015 revision considers customers, owners, providers, bankers, unions, regulators, partners in society groups, competitors, and even pressure groups all as potential "interested parties" who may be affected by decisions made by your company, or the scope of your QMS. For example, if you made a business decision to ramp up your organization's activities by having a 24-hour shift pattern, then local residents who may be affected by increased traffic or activity to and from your site would then become an "interested party." You must be able to demonstrate that you have taken all these factors into consideration to satisfy this clause.

In folder 02 List of all interested parties, you will find the record named List of Interested Parties, which contains examples and comments that will help you meet this requirement.

Read more here: How to determine interested parties and their requirements according to ISO 9001:2015.

3) Determining the scope of the QMS

Having an effective QMS depends directly on how you define the scope and parameters in the embryonic stages. Likewise, the transition period from revisions 2008 to 2015 provides an opportunity to ensure this is done correctly and accurately. For example, it is easy to consider all the internal issues within your QMS definition, but do you know all you need to know in order to clearly define the external issues that are related to your outsourcing partners and supply chain? Demonstration of all of these aspects must be provided when you define the scope of your QMS.

In folder 03 Determine the scope of the QMS, you will find the document called Scope of the QMS, which contains comments that will help you meet this requirement.

For more information, see: How to define the scope of the QMS according to ISO 9001:2015.

4) Demonstrate leadership

There is a marked change in the "leadership" requirements in the 2015 revision, which appear in clause 5. The 2015 revision calls for leaders to be "active" and responsible, rather than the more passive role that could be interpreted from the 2008 revision. The 2015 revision assigns responsibility to the organizational leader for strategic quality objectives, QMS scope and results, policies and processes, communication, culture, fostering a commitment to quality, providing resources and training opportunity, and even "inspiring, encouraging and recognizing the contribution of people." Therefore, it is clear that "top management" involvement and inclusion in all aspects of your QMS will become a requirement. For instance, making decisions on issues like risk assessment topics will now be almost impossible without strategic leadership advice, except in the instance of responding to an "incident."

Clause 5 of ISO 9001:2015 is one of the clauses that cannot be addressed with one single document, but indirectly through providing resources, taking accountability for the QMS effectiveness; promoting a process approach and risk-based thinking; engaging, directing, and supporting persons; promoting improvement; and finally, formulating a Quality Policy.

Requirements for the Quality Policy haven't significantly changed; however, there are additional requirements compared to the previous version of the standard. In folder 04 Demonstrate leadership, you will find the policy document that contains comments that will help you meet this requirement.

Read more at: How to comply with new leadership requirements in ISO 9001:2015.

5) Align QMS objectives with the company's strategy

The 2015 revision requires the organization to ensure that the quality objectives are compatible with the strategic direction of the company. The revision also requires that the plans for achieving the objectives must be created. Therefore, it is critical that you document this plan for audit purposes against the 2015 standard. For example, does your business plan mention QMS objectives? The success of both will be more dependent on each other than before in terms of the 2015 version of the standard.

In folder 05 Align QMS objectives with the company's strategy, you will find the record for Quality Objectives, which contains examples and comments that will help you meet this requirement.

Read more at: How to Write Good Quality Objectives.

6) Assess risks and opportunities

This is a new and key requirement of the 2015 revision, and appears in clause 6 of the 2015 standard. Risks and opportunities now need to be considered for all aspects of the QMS, including all compliance requirements and even the context of the organization. After this, there should be a documented plan on how the business should address that risk. Therefore, the assessment of risk and opportunity is intended to become an integral part of all major QMS components and decision-making processes. Add this to the increased reliance on leadership mentioned above, and it is easy to see how real business benefits will be attained for most organizations.

Although clause 6.1 Risks and opportunities does not require application of any risk assessment methodology or documented procedure, it is recommended to create a procedure that will provide a systematic approach to identification and evaluation of risks and opportunities.

In folder 06 Assess risks and opportunities, you will find a procedure that will help you implement risk-based thinking together with a registry of key risks and opportunities and a procedure for applying FMEA, as the most popular risk assessment tool.

Read more at: How to address risks and opportunities in ISO 9001.

7) Control documented information

Procedures and records are now defined under the new term "documented information." During the process of aligning your existing documentation to the new clause numbers, the transition from 2008 to 2015 is a perfect opportunity to improve your existing documentation. For example, as "documented information" and a "process approach" are now critical, why not consider replacing some of your more wordy or cumbersome process instructions with one single process diagram? While improving your documentation is an excellent opportunity to demonstrate continual improvement, you are advised to ensure that your existing documentation still meets the needs of the 2015 revision.

The new version of the standard combines requirements for documents and records control into a single clause, treating them in the same way. Although many companies already have a well-defined document and record control process, the new ISO 9001 prescribes rules for each phase in document and record control – from creating and updating, to storage, preservation, retention, and disposition. The previous version of our Procedure for Document and Record Control has already fulfilled most of the requirements of the new ISO 9001, so most of the changes are not visible through track changes, but through comments explaining the requirements and how they are met with the procedure.

In folder 07 Control documented information, you will find the procedure along with the records needed to make it work.

Read more at: New approach to document and record control in ISO 9001:2015.

8) Operational Control

Improved operational control versus the stated criteria is one of the goals of the 2015 revision. The stated criteria are that your organization must define the criteria and processes for services and products to be effectively delivered, and ensure that the documentation and resources to deliver them are in place. Therefore, it is important that your process documentation reflects this improved accuracy and operational control to comply with the new standard. For example, are your stated criteria and defined processes aligned to produce the targeted results and outcomes? Can you show that resources have been planned and delivered and that the product conforms to the stated requirements?

All these new requirements for process control must be implemented in all processes of the organization. The new version of ISO 9001 has more specific requirements regarding the production and service provision, in terms of defining necessary documented information, resources, responsibilities and release, delivery and post-delivery activities.

In folder 08 Operational control, you will find the Procedure for Production and Service Provision, with clearly marked changes that need to be made along with records needed for full compliance with ISO 9001:2015 clause 8.5 Production and service provision.

For more information, see: ISO 9001:2015 clause 8.5 Product realization – Practical examples for compliance.

9) Review the design and development process

There is a marked change in the level of control the 2015 standard requires in terms of design and development relative to the 2008 version. Responsibilities, inputs and outputs, controls, change control, change authorization, and action required to prevent adverse impacts are among the factors that now need specific consideration. Documentation of these aspects is also critical. For example, if you have a product that has changed in terms of specification, can you evidence who authorized and approved that change, and provide documented proof that shows that person is deemed "qualified" to do so? This is the level of detail that this clause demands to protect the integrity of the process and product, and the needs of your customer.

In folder 09 Review design and development process, you will find the procedure with track changes and comments explaining what need to be done in order to align your design and development process with ISO 9001:2015.

10) Control of external providers

Clause 8.4 of the 2015 standard is "Control of externally provided processes, products and services," and replaces what was "Purchasing" in the 2008 standard. The main thread is that you must ensure that your organization's externally provided products and services fulfill your stated requirements. Therefore, your organization must determine what type and extent of controls and related information need to be provided to any external parties to ensure their delivery matches your requirements exactly. For example, can you illustrate an exact specification, timescale, quality expectation, and cost for an outsourced product? ISO 9001:2015 requires this to be done, documented, and implemented.

The new version of the standard now prescribes rules for control of not only suppliers, but also outsourcing partners. By widening the scope of the purchasing procedure, and adding new controls and requirements towards outsourcing partners and suppliers, the purchasing process will achieve compliance with the new version of ISO 9001.

In folder 10 Control of external providers, you will find the procedure along with the records needed to make it work.

Read more at: How to control outsourced processes using ISO 9001.

11) Performance evaluation

Clause 9 of the 2015 revision deals with "Performance Evaluation." There is now a requirement to evaluate the effectiveness and performance of your QMS, in a similar way that key performance indicators have been used elsewhere in the past. Again, your organization is required to keep documented evidence of the results; so, for instance, continual improvement can be developed from this process.

In folder 11 Performance evaluation, you will find the Matrix of Key Performance Indicators that will help you monitor your process's performance, as well as the Data Analysis Report that will help you formulate additional data necessary for management review.

For more information, see: How to define Key Performance Indicators for a QMS based on ISO 9001.

12) Measuring and reporting

Requirements for both measuring and reporting across several clauses of the 2015 standard have become more specific. Measurement within processes such as Management Review and Internal Audit now need to be aligned with the 2015 standard. Techniques of both of these processes are not affected, rather the input elements for the Management Review and the elements to be audited during the Internal Audit. So, for example, the standard aspires to make these functions "measureable" in a way they may not have been previously, which opens the pathway for implementing improvement.

In folder 12 Measuring and reporting, you will find the Procedure for Management Review that contains all inputs and outputs required by the new version of ISO 9001 with comments that will help you meet this requirement. Since the internal audit process hasn't changed, only the requirements to be audited are changed, and for that purpose you can find the Internal Audit Checklist in the folder called Before you start.

Once the internal audit is conducted and all nonconformities are identified, you will need to initiate and conduct corrective actions. In the same folder, you will find Procedure for Management of Nonconformities and Corrective actions together with all the records needed for effective management of nonconformities and corrective actions.

For more information, see: How to implement the Check phase (performance evaluation) in the QMS according to ISO 9001:2015.

Wrap up the project

Although the Quality Manual is no longer a mandatory document according to ISO 9001:2015, many organizations find it useful and decided to keep it as a part of their Quality Management System – for that reason, we decided to include the Quality Manual in our Transition toolkit. In folder 08 Quality Manual, you will find a completely revised Quality Manual, aligned with ISO 9001:2015 with comments on each clause and an explanation of changes compared to the previous version of ISO 9001.

Read more at The future of the Quality Manual in ISO 9001:2015.

Advisera

9001 Academy
ISO 9001 Online Consultation Center

EPPS Services Ltd.
for electronic business and business consulting
UI. Zavizanska 12, 10000 Zagreb
Croatia, European Union

Email: info@advisera.com
Phone: +1 (646) 759 9933
Toll-Free (U.S. and Canada): 1-888-553-2256
Toll-Free (United Kingdom): 0800 808 5485
Fax: +385 1 556 0711

EXPLORE THE ACADEMIES

27001 Academy
ISO 27001 and ISO 22301 Online Consultation Center

14001 Academy
ISO 14001 Online Consultation Center

20000 Academy
ITIL and ISO 20000 Online Consultation Center

18001 Academy
OHSAS 18001 Online Consultation Center