Quality Management System Guidance

ISO 9001:2015 Clause-by-clause Interpretation

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1   Introduction

The purpose of this document is to outline a potential quality management system to meet the requirements of ISO 9001:2015. The quality management system is designed to be implemented to function within current business practices and to serve as an effective tool to help your business grow and improve.

The Figure below illustrates our methodology for the development of your QMS; using the plan, do, check and act process approach, to implement and deliver management system objectives, stakeholder requirements and customer satisfaction.

Figure 1: ISO 9001:2015 QMS & PDCA Interaction

Internal & External Issues	Needs & Expectations of Interested Parties

Context of the Organization

Scope of the QMS

Planning

PLAN

Operation

Leadership & Commitment

ACT

Improvement

DO

Support & Operation

CHECK

Performance Evaluation
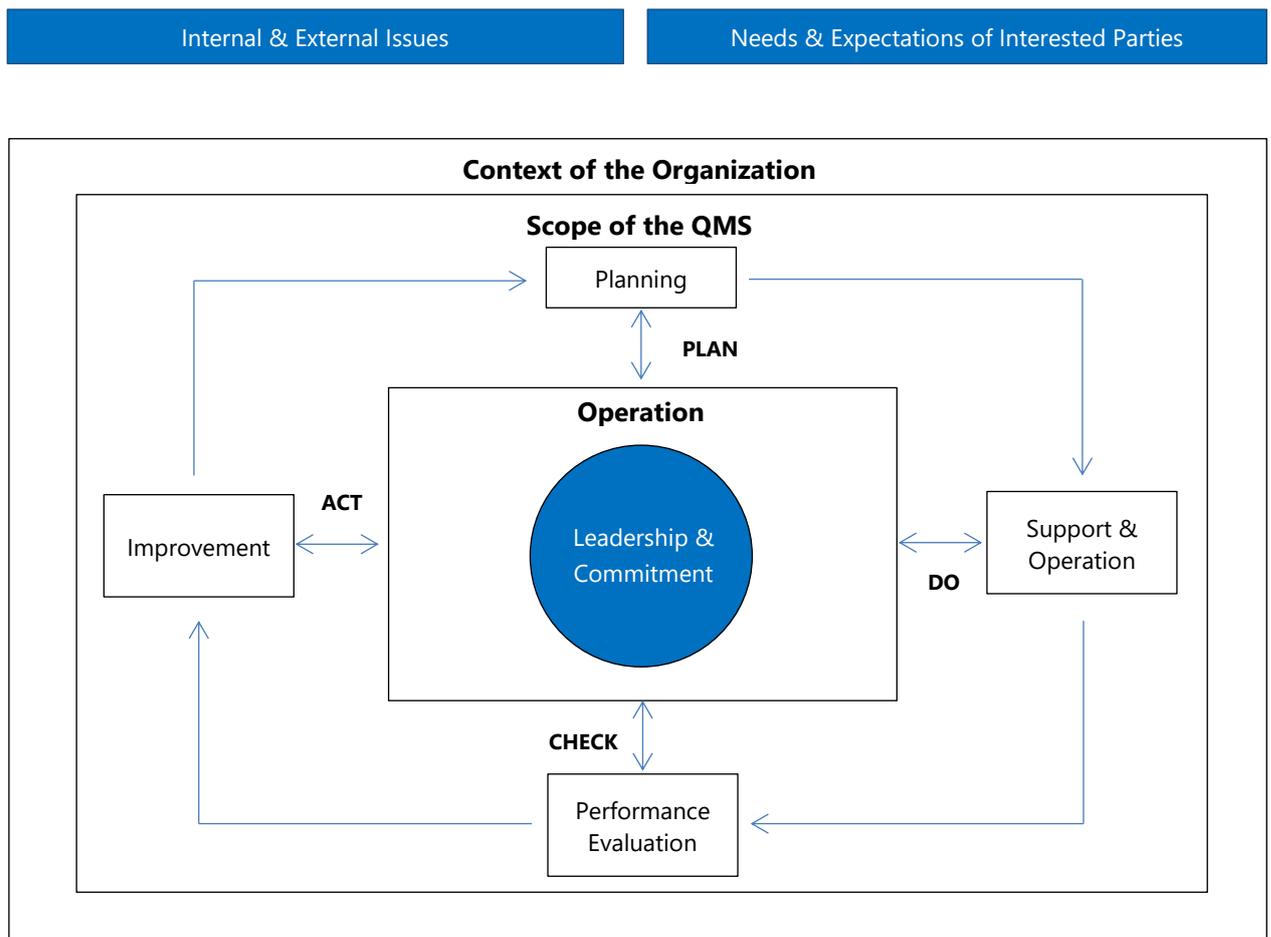
The application of the quality management system is scalable and generic; regardless of the size and type of organization. The elements that form a typical the QMS are the same; please refer to the figure below. The primary goal is to achieve a set of consistent processes that provide a route for enhancing customer satisfaction, mitigation uncertainty and providing meaningful data for continuous improvement activities.

You may decide to keep your current quality management system and simply amend them where necessary. Some of you may take this as an opportunity for a complete revamp of the management system. Both courses of action are entirely reasonable, and this guidance document will guide you through what the essential elements that you need to address in order become certified.

4 About Your Organization

4.1 Organizational Context

You should allow additional time to establish a suitable understanding of the circumstances, and the market in which your organization operates. To be compliant, evidence should be obtained that demonstrates that your organization is reviewing all pertinent internal and external issues at periodic intervals.

To assess whether your organisation has a high-level, conceptual understanding of its internal and external issues that affect it, either positively or negatively, its ability to achieve the intended outcomes, you should describe the processes used by your organization to identify internal and external issues and make reference to all objective evidence, including examples of these issues. Examples of organizational issues might include:

1. Quality conditions capable of affecting or being affected by the organization;
2. External: cultural, social, political, regulatory, financial, economic, natural and competitive issues, whether international, national, regional or local;
3. Internal: organization's activities, products, services, strategic direction and capabilities (people, knowledge, processes, systems).

You will need to determine and understand the various quality conditions, internal and external issues, typically experienced in your type of organization that can have positive or negative impacts.

The standards do not specify that these internal and external issues, or their monitoring and review, be documented, so there might not be 'lists of issues' or records of reviews. However, information can be obtained via interviews with relevant Top management in relation to your organization's context and its strategic direction, the identified issues and conditions, and how these may affect the intended outcomes of the Management System.

Collate evidence to provide assurance that your organization is regularly, or as necessary, reviewing and updating its external and internal issues. Although there is no requirement for documented information to define the context of the organization, your organization will find it helpful to retain the types of documented information listed below to help demonstrate compliance:

1. Business plans and strategy reviews;
2. Competitor analysis;
3. Economic reports from business sectors or consultant's reports;
4. SWOT analysis for internal issues;
5. PESTLE analysis for external issues;
6. List of external and internal QMS issues and conditions.
7. QMS action plans and objectives;
8. Annual reports;
9. Minutes of meetings (Management review and, e.g. design review minutes);
10. Process maps, tables, spreadsheets, mind mapping diagrams.

Reviewing your organization's context could include interviews with senior management, questionnaires, surveys and research. Cross-functional input is essential for the specific expertise required to identify the full breadth of issues, such as finance, training, human resources, commercial, engineering and design, etc. Not

5.0 Leadership

5.1 Leadership & Commitment

5.1.1 QMS Management

You should seek and record evidence that Top management is taking a 'hands-on' approach to the management of the QMS. Be prepared to constructively challenge Top management's commitment to the QMS. Auditing this tier of management is likely to be a new experience for many people, so it is important that you have a good understanding of management activities in order to effectively engage with them.

Top management is now required to emphasize the importance of conforming to the QMS requirements. Additionally, it must also ensure that the QMS is achieving its intended results, and that continual improvement is driven within the organization. If it is evident that the Top management is not involved with the QMS, a major non-conformance is likely.

Auditors should look for evidence that top management has a 'hands-on' approach to the management of their QMS during interviews and auditing other requirements e.g. Context of the organization, policies and objectives, Management review minutes, Resources etc. Evidence of Top management involvement may be found in:

1. Business strategy plans and meetings;
2. al goals and communications;
3. Information provided on the organization's website;
4. Annual reports;
5. Management meeting minutes.

Management involvement must now be demonstrated and cannot be simply confined to annual management reviews. Auditors should ensure that they are well prepared to interview the Top management in respect of their commitment to their QMS. A good understanding of management-related processes and language used by Top management can be helpful to engage with management on a range of issues.

Without solid management commitment, you will not have a successful quality management system. This is not a commitment in words; it is the continuous and active demonstration to everyone in the organization that the need to meet customers' expectations is vital. The actions required of Top management include:

1. Supporting QMS and actively promote the agenda;
2. Encouraging the goal of meeting, customer, regulatory and statutory requirements.

Develop and support the QMS by:

1. Defining and communicate the QMS policies;
2. Establishing organizational QMS objectives;
3. Ensuring appropriate resources are available.

Implement and improve the QMS by:

1. Encouraging employees to achieve requirements;
2. Reviewing QMS performance;
3. Ensuring resources are available to improve the QMS.

6.0 QMS Planning

6.1 General

6.1.1 Actions to Address Risks & Opportunities

Although risks and opportunities have to be determined and addressed, there is no requirement for a formal, documented risk management process. Confirm that your organization has a methodology in place that enables them to effectively identify risks and opportunities with respect to the planning of its QMS. Reference to risk-based thinking is present in the following clauses of the standards:

1. Determine and address risks (Clause 4.4.1);
2. Promote risk-based thinking (Clause 5.1.1);
3. Ensure risks determined and addressed (Clause 5.1.2);
4. Determine risks that need to be addressed to achieve intended results (Clause 6.1.1);
5. Plan actions to address risks; integrate into processes; evaluate effectiveness of actions (Clause 6.1.2);
6. Control those risks identified (Clause 8.1);
7. Evaluate effectiveness of actions on risks (Clause 9.1.3);
8. Review effectiveness of actions on risks (Clause 9.3.2);
9. Improve the QMS responding to risk (Clause 10.3);

The risks and opportunities should be relevant to the context of your organization (Clause 4.1), as well as, any interested parties (Clause 4.2). You should ensure that your organization has applied this risk identification methodology consistently and effectively.

What process has been developed to identify risks and opportunities? In the absence of documented processes/procedures, you may need to use observations and interviews (and a review of the process output, which may contain documented evidence) to assess the processes that determine whether or not undocumented processes are being carried out as planned.

External and internal issues, and relevant needs and expectations of relevant interested parties may be sources of risks. Objective evidence may be in the form of a dedicated risk matrix, risks added to other forms such as corrective action reports, etc. All of the processes of your QMS do not represent the same level of risk in terms of your organization's ability to meet its objectives. Due to this reason, the consequences of failures or non-conformities in relation to processes, systems, products and/or services will not be the same for all organizations.

When deciding how to plan and control the QMS, including its component processes and activities, your organization needs to consider both the type and level of risk associated with them. Ensure that your organization is taking a planned approach to addressing risks and realizing opportunities, and that any actions taken have been recorded. Options to address risks and opportunities can include:

1. Avoiding risk;
2. Taking risk in order to pursue an opportunity;
3. Eliminating the risk source;
4. Changing the likelihood or consequences;
5. Sharing the risk;
6. Retaining risk by informed decision;

7.0 Support

7.1 Resources

Ensure that your organization has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. Check that your organization has identified which resources it needs to make available in order to ensure the effective operation of the QMS. Resources will often include raw materials, infrastructure, finance, personnel and IT, all of which can be either internally or externally provided.

Auditors may look at the budget to check that some funding has been allocated to the QMS but they might dig deeper, checking if the organization has really identified all types of resources required and that it has taken action to ensure that those resources are available as needed.

7.1.1 General

You should seek and record evidence conforming that your organization has considered the need for external resources in addition to the need for internal resources. Most organizations determine resource requirements during management review meetings; you should review the management review minutes for evidence of resource allocation.

7.1.2 People

You should seek and record evidence to confirm that your organization has provided the staff necessary for the effective implementation of the QMS and for the operation and control of its processes.

7.1.3 Infrastructure

You should seek and record evidence to confirm that your organization has provided the infrastructure necessary for the effective implementation of the QMS and for the operation and control of its processes. Identify, provide and maintain infrastructure requirements necessary to achieve product conformance:

1. Buildings and workspaces;
2. Tools and process equipment, e.g. hardware or software;
3. Supporting services, e.g. transport, I.T. and communication.

7.1.4 Environment for the Operation of Processes

You should seek and record evidence to confirm that your organization has identified, provided and maintained the infrastructure necessary for achieving product conformance. Provide a work environment that allows the achievement of product conformity, consider the following factors:

1. A place of work that is safe, including all equipment and methods of work;
2. Training, instruction, information and supervision for employees;
3. A means of safe handling, storage, use and transportation of equipment, materials and chemicals;
4. Safe working environment with good lighting, ventilation, safe passageways, stairs and corridors.

All employees must:

1. Protect themselves and co-workers who may be affected by their actions and behavior;
2. Use appropriate personal protective equipment (PPE) and/or clothing provided;

8.0 Operation

8.1 Operational Planning & Control

This requirement is comparable to the requirements from ISO 9001:2008 Clause 7.1 – Product Realization Planning, but it has been extended to include implementation and control, as well planning. You should seek and record evidence that your organization has determined the design and its processes to meet the requirements of your customers and the requirements of your QMS. Evidence that the process, including all inputs, outputs, resources, controls, criteria, and process measurement and performance indicators being planned should be sought.

For those risks and opportunities that your organization has identified, you should seek evidence that these actions have been integrated into the management system; as such, these actions should be verifiable at process level – for example, evidence of controls, acceptance criteria and resources to address the risks and opportunities. Review the acceptability criteria; this may include targets, measures, values, KPIs, specifications and other criteria as relevant to the output.

You should ensure that the implemented processes are controlled as planned and that there is evidence that your organization has evaluated the effectiveness of actions taken when addressing risks and opportunities. Evaluate and record any evidence pertaining to planned and unintended changes.

Operational planning is about controlling the design and development process. The organization must ensure that all related activities take place under controlled conditions. The final product or service is the culmination of events that transfer customer requirements and expectations into a tangible product or effective service that conforms to specified requirements and expectations. Control product realization planning by:

1. Determining quality objectives for the product;
2. Determining requirements for the product;
3. Identifying processes required to achieve conformance;
4. Establishing processes required to achieve conformance;
5. Identifying documents to demonstrate conformance;
6. Identifying resources required to achieve conformance;
7. Maintaining and retaining documented information.

Your organization needs to plan in advance for how they will manufacture their product or deliver their service. The plans need to take into account the product requirements and any quality objectives that might be appropriate, resources and documents that may be necessary, what type of monitoring and/or inspection activities should be put in place to ensure the product or service will meet the requirements, and what types of records should be kept.

8.2 Requirements for Products & Services

8.2.1 Customer Communication

This requirement is directly comparable to the requirements of ISO 9001:2008 Clause 7.2.3 – Customer Communication. It has been expanded to include new requirements to obtain 'customer views and perceptions' instead of 'customer feedback'. Some or all of the following specific customer communication should be observed and evidenced:

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis & Evaluation

9.1.1 General

The organization has to determine what it needs to monitor and measure. This includes the determination of the criteria against which the quality performance will be evaluated including appropriate indicators. How does your organization carry out these monitoring and measurement activities in order to ensure that the results obtained are valid?

These methods may include, as appropriate, statistical techniques to be applied to the analysis of those results. When monitoring and measurement should be carried out and at what stage the results of monitoring and measurement should be analyzed and evaluated.

You should note the **additional requirement** for your organization to evidence evaluation of the results of monitoring and measurement, not just their analysis. They should confirm that the organization has considered what, how and when to measure and that the outcomes from this decision result are ensuring appropriate process control.

Also note a **new requirement** to monitor the performance and effectiveness of your organization's QMS. You should expect to see that your organization has developed a process (method, techniques, format, etc.) to identify, collect and analyze various data and information from both internal and external sources, including:

1. QMS records;
2. Monitoring and measuring results;
3. Process performance results;
4. Meeting objectives;
5. Internal audit findings;
6. Customer surveys and feedback;
7. 2nd or 3rd party audit results;
8. Competitor and benchmarking information;
9. Product test results;
10. Supplier performance information.

This 'input' (information and data) should reflect upon the adequacy, suitability and effectiveness of the quality management system and its processes. The 'output' (result of the analysis) must provide information (understanding, insight, awareness, confidence, knowledge of, etc.). The analysis output must provide insight to:

1. Customer satisfaction and perception;
2. Product conformance;
3. Process performance;
4. Product and process characteristics;
5. Trends in products and processes;
6. Opportunities for preventive action;
7. Suppliers and subcontractors.

10.0 Improvement

10.1 General

Your organization should actively seek out and realize improvement opportunities that will better enable it to achieve the intended outcomes of its QMS. Potential sources of improvement opportunities include the results of analysis and evaluation of quality performance, compliance, internal audits and management reviews.

Improvement often does not take place on a 'continual' basis. Sometimes improvement can be afected reactively through corrective actions, incrementally overtime, by a step change or breakthrough, creatively through innovation or by re-organization and transformation. Look out for objective evidence that improvement is taking place. However, while improvement does not need to be continuous, it does need to be evidenced as occurring.

10.2 Non-conformity & Corrective Action

The requirements of Clause 10.2.1 are comparable to ISO 9001:2008 Clause 8.3 - Control of Non-conforming Product and Clause 8.5.2 - Corrective Action. There is an additional requirement for your organization to determine whether other similar non-conformances exist or have the potential to exist that may affect product, process or QMS conformity. There is also a new requirement for your organization to determine whether changes to the QMS are required to prevent a reoccurrence. Your organization is now required to:

1. Take whatever action is necessary to control and correct the non-conformity, and to deal with any resultant impact;
2. Determine what caused the non-conformity and then to consider whether the potential for a similar problem remains;
3. Consider whether any further action is required to prevent a similar non-conformity recurring at the same place or occurring somewhere else, at some point in the future;
4. Determine if similar non-conformity has occurred elsewhere and consequently whether it needs to take similar corrective action.

There may be instances where it is impossible to completely eliminate the cause of non-conformity, so in instances, the best organizations can do is to reduce the likelihood or the consequences of a similar occurrence happening again in order to reduce the risk to an acceptable level.

Modify the necessary systems, policies, practices and procedures to prevent recurrence of problems and similar ones. Make recommendations for systemic improvements as necessary:

1. Review the history of the problem;
2. Analyze how the problem occurred and escaped;
3. Identify affected parties;
4. Identify opportunities for similar problems to occur and escape;
5. Identify practices and procedures that allowed the problem to occur;
6. Identify practices/procedures that allowed the problem to escape to the customer;
7. Analyze how similar problems could be addressed;
8. Identify and choose appropriate preventive actions;
9. Verify preventive action and its effectiveness;
10. Develop action plan;