



**Add value.
Inspire trust.**

Quality at a glance

ISO 9001:2015 Guidance
Updated version 2021



Foreword

Quality management (QM) is a key topic for every business. Only organizations which manage their quality effectively will succeed in the market. But how to ensure high quality and customer satisfaction? Through a management system based on ISO 9001 – the most widespread QM standard worldwide.

This updated guidance addresses entrepreneurs, consultants, and anyone planning to establish, certify, and continually improve a quality management system (QMS) according to ISO 9001. It explains the requirements of the ISO 9001:2015 standard in clear terms, provides guidance, and supports users with implementation of the standard in practice.

The guidance comprises two parts:

Part 1 deals with the structure of the QM standards and gives an overview of its key characteristics.

Part 2 provides practical interpretation of the individual requirements, underpinned with examples of audit questions and notes on the required documented information.

The period for transition from the ISO 9001:2008 to the ISO 9001:2015 standard expired in 2018, so that comparison of these two standards no longer provides added value. We therefore now offer an updated version of our ISO 9001 guidance, which focuses wholly on the current version of the standard.

We wish you the best of success in your work with the ISO 9001:2015 standard!

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ISO 9001:2015 audits are carried out in accordance with the ISO 9001:2015 standard, not on the basis of this guidance.

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Part 1 – Introduction to ISO 9001:2015

1 Introduction

Increasing operational transparency, improving processes, sustainably enhancing customer satisfaction, reducing rates of defects and rejects – the list of arguments for operating a certified quality management system is a long one. Business and industry have come to share this understanding over time, turning QM into a clear must-have. While companies 50 years ago would have balked at giving external parties insight into their production processes, an ISO 9001 certificate has today become a basic requirement of many customers, including – but not confined to – the manufacturing industry. The standard itself has undergone repeated revisions with the International Standards Organization (ISO), aligning it to the latest developments in society, business, and industry and adapting it to new conditions.

The 5th revision of the ISO 9001 standard, which applies at present, was published on September 15, 2015. Its “High Level Structure,” which has been adopted for all “major” management system standards, makes the ISO 9001:2015 easy to use as basis of an integrated management system. In terms of content the standard places greater emphasis on the context of the organization, interested parties, the risk-based approach, and the handling of knowledge. It gives considerably greater responsibility for the management system to the board of management or “top management,” and focuses more closely on the topic of services. The following chapters will discuss these and many other aspects in depth.

2 Milestones of development

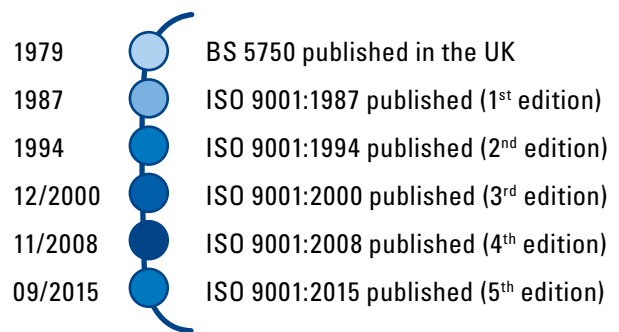
The origins of ISO 9001 go back to the need of the global armaments industry for quality-assurance guidelines.

The 2nd revision brought a change in perspective. Instead of merely testing the quality of the finished product, ISO 9001:1994 also focused on the significance of preventive actions in improving product quality.

ISO 9001:2000 concentrated on quality management rather than quality control. To do so, the standard started by analyzing the requirements of the organization before designing the associated processes. The standard centered on continual process improvement and the significance of customer satisfaction.

The current version of the standard ISO 9001:2015 is the result of the standard’s consistent further development toward becoming a comprehensive, integrated element of corporate management. It provides top management (Management Board) with tools for achieving the intended objectives.

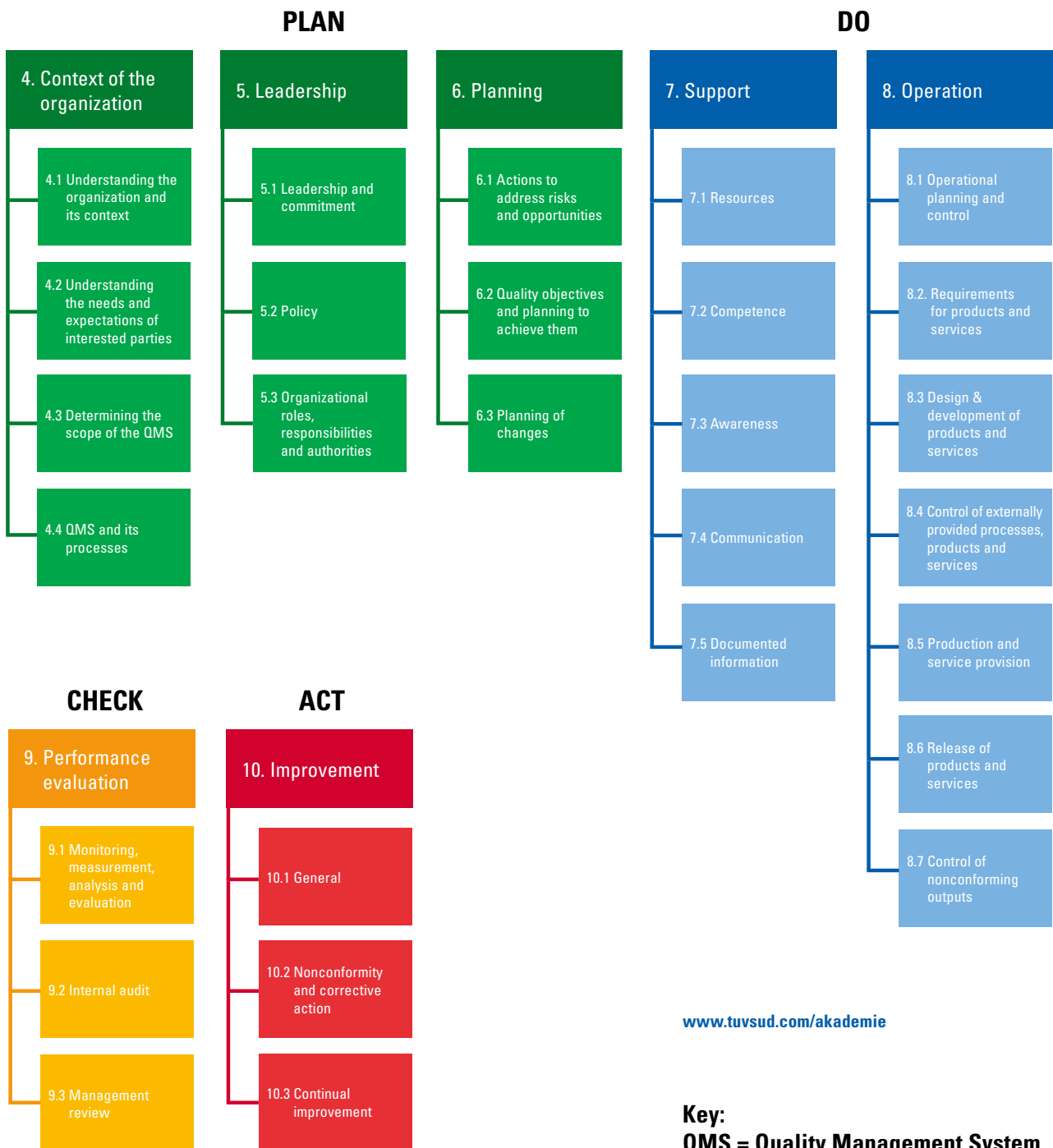
Development of ISO 9001:



3 High Level Structure

ISO 9001 follows the High Level Structure which shares an identical sequence of clauses, text and terminology with other management system standards, e.g. ISO 14001:2015 (Environmental Management System). The high-level structure aims at achieving consistent structure across all management-system standards (MSS) to improve the mutual compatibility of management systems.

The standard comprises 10 clauses: Clauses 1 to 3 address the scope, normative references and terms and definitions. Clauses 4 to 10 form the P-D-C-A cycle (Plan – Do – Check – Act).



4 Non-applicable elements of the standard

ISO 9001:2015 no longer permits exclusions. All clauses of the standard applicable to the organisation must be included in certification. However, if the organisation can provide justification that one or more clauses are not relevant to them, these elements need not be applied. The justification must be in writing to be effective. Conversely, this means that the justification must show how the organization manages to produce conforming products and services and improve customer satisfaction without applying that clause/those clauses. Non-application of one or several clauses must not negatively impact on the organization's purpose or on applicable statutory, regulatory, or other requirements.

If the major part of design and development is performed by an external provider, the organization must prove that it has substantial control of the design and development process.

Project management or process development are not considered design and development as defined in ISO 9001 unless they influence the organization's product or service. Given this, there is no explicit requirement to apply clause 8.3 of the standard in this case. Application is optional.

Two examples, one from the service sector (healthcare/ medical practice) and one from production are used to explain design and development and its assessment as set forth in clause 8.3.

Service	Production
No design and development:	
Installation of a new patient call system. Carried out within the scope of a project. The service provided by the medical practice remains unchanged; only the communication with the patient is facilitated/improved.	Implementation of the 5 S methodology in production. Within the scope of a project, workplaces are restructured within production operations to reduce waste (time, material, etc.) and improve production efficiency.
Not every project or process change is to be automatically understood as design and development.	
Design and development:	
Development of a new treatment method within the scope of a university research project.	Design and development of a new vehicle engine, e.g. taking into account changing emission standards.
These projects clearly fall under the definition of design and development.	
Design and development not mandatory:	
Introduction of a new treatment method. According to the above criteria, the introduction of a new treatment method can be regarded as design and development as defined in the standard. Other process developments which are carried out within the scope of a project can also be classified under this clause.	New casting process for a new engine piston cylinder liner. The process is aligned to the new technical requirements (outputs of the design and development process) and can, but need not, be part of a higher level design and development project.
Application of clause 8.3 is not mandatory in these cases.	

Design and development as defined in ISO 9001:2015, clause 8.3

Design & development of a new product/service (e.g. a new treatment method within the scope of university research)

MUST

No design and development as defined in ISO 9001:2015, clause 8.3

Introduction of an already developed new service (e.g. introduction of a new treatment method that has not been developed in-house)

Process development
(e.g. through the use of project management)

CAN

The likelihood of clause 8.5.3 “Property belonging to customers” not being applicable is very small. In the healthcare system, for example, this clause is always applicable. According to the note to clause 8.5.3 customer’s property can also include personal data.

Examples of standard elements that may not be applicable, for example in case of multi-site organizations with differing scopes at the individual sites, include:

- 7.1.5 Monitoring and measuring resources
- 8.3 Design and development of products and services
- 8.4.1 Control of externally provided processes, products, and services (e.g. purchasing for the entire organization is centralized at one site, thus the requirement is not applied at sites without purchasing function)
- 8.5.2 Identification and traceability (e.g. for some services)
- 8.5.3 Property belonging to customers or external providers
- 8.5.4 Preservation (e.g. for some services)



5 QM principles

A common understanding is necessary to fulfill the organization's strategic approach. The seven QM principles form the basis of the requirements of ISO 9001:2015.

Customer focus

Customers are at the centre of every corporate activity. They decide success or failure. Given this, understanding the needs of customers and ensuring that their expectations are not only fulfilled but exceeded where possible, is important.

Leadership

Executives at all levels are responsible for aligning the organization to the requirements of the market. To do so, they must establish and maintain an internal environment, in which employees are fully motivated and engage in achieving the corporate objectives.

Engagement of people

The character of an organization is determined by employees across all levels. Appreciation, empowerment and support are critical to ensure employees are motivated to invest their skills and expertise for the good of the organization.

Process approach

To reach the requested output more efficiently, there should be clear interrelationships and interdependencies between all activities and the associated resources.

Relationship management

Organizations and their interested parties (e. g. suppliers) depend on each other. Given this, fair and transparent relationships based on mutual trust are important and form the basis of sustainable success.

Evidence-based decision making

Exact analysis of data and information forms the basis for understanding cause and effect relationships and their possible consequences and for implementing effective actions.

Improvement

Only organizations that challenge themselves and continually improve their overall performance will be able to realize long-term success.

6 Responsibilities of top management

ISO 9001:2015 clearly expanded the requirements for leadership, leadership roles and responsibility. Top management is now accountable for the effectiveness, maintenance and continual improvement of the QMS. A Quality Management Representative (QMR) is no longer absolutely necessary. While responsibility itself cannot be delegated, individual tasks can still be assigned to a management representative.

Lived and breathed quality culture is to be spread to the organization from the top, i.e. from management. Given this, top management is also responsible for promoting improvement and ensuring the achievement of the expected outputs. Top management must also ensure provision of the resources needed (including the necessary knowledge).

In this context, top management is accountable for quality culture both within the organization and in the organization's external relationship towards the customer. Integration of understanding for the customer, the customer's perspective and the relevant statutory and regulatory requirements into the organization forms part of the responsibilities of top management.

Quality management policy and objectives not only need to be established and communicated, but also need to be compatible with the context of the organization and its strategic direction; objectives need to be planned and cascaded.

Given this, audit planning should allow more time for the auditing of top management.

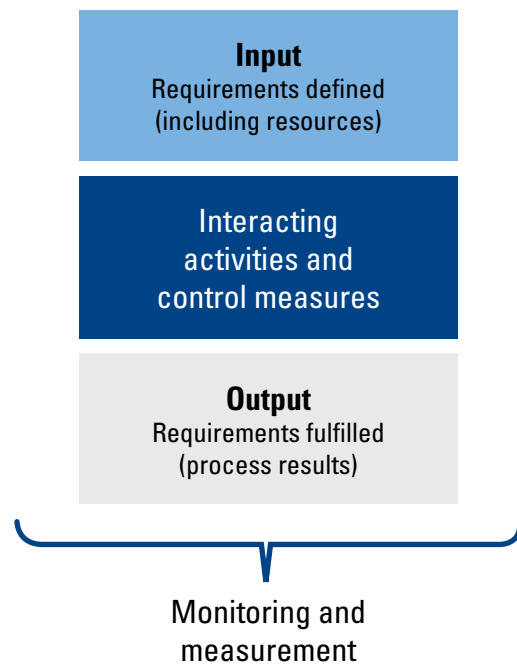
7 Process approach

The process approach ensures that application of the standard is easy and does not depend on the organization's size or purpose. The process approach improves the organization's effectiveness and efficiency in achieving the intended objectives. Expectations are fulfilled and customer satisfaction thus improved.

A process is a set of interrelated and interdependent activities that transform inputs into outputs.

The process approach enables an organization to:

- improve its understanding and consistency in meeting requirements (improved, consistent, and predictable results)
- create added value (reduced costs and shorter cycle times based on the effective use of resources)
- achieve effective key performance indicators (KPIs)
- improve processes based on the evaluation of data and information
- promote employee participation and clear responsibilities



8 Process maturity

To ensure a high level of process quality, the following quality characteristics should be available and effective in an organization.

PDCA Cycle	Requirements/Criteria	Possible implementation in practice
<p>ACT ^ CHECK ^ DO ^ ^ ^ PLAN</p>	Process + QMS improvement	CIP workshops, process analysis, internal audits
	Monitoring and measurement	ERP system, SPC, KPIs
	Effective implementation and control	Workflow system, ERP system, instructions
	Risks + opportunities	Process sheet, risk matrix, turtle
	Availability + resources	HR scheduling, investment planning
	Responsibility + authorities	Workflow system, ERP system, responsibility matrix
Inputs + outputs	Workflow, ERP system, DPs	
Sequence + interactions	Process map, workflow, ERP system	

Sequence and interactions, inputs and outputs

In steps one and two, the organizations must define the inputs and intended outputs of their processes and determine their sequence and interactions, e.g. in a process map or individual process sheets.

Responsibility and authority

In step 3, the organization must also review the responsibilities and authorities for these processes, using tools such as responsibility matrices.

Availability and resources

Once this is completed, in step four organizations are expected to identify the technological and human resources needed. Important aspects in this context include personnel and investment planning for responding appropriately to cases such as evident fluctuations or planned market expansion.

Risks and opportunities

Step five of process maturity focuses on risk-based thinking. To this end, organizations must verify that they have identified all risks relevant for the key processes. Beyond the financial risks already analyzed by many companies, there are other risks including the availability of expertise among knowledge owners and specialists, or market risks caused by more innovative competitors. A quality management system according to the new ISO 9001 typically identifies these risks in direct association with the established processes. For risk identification, the detail-oriented process focus should be expanded to take in the whole picture, particularly including customers' expectations and the context of the organization.

Effective implementation and control

Effective process operation and control must be ensured in step six. This requires clear instructions, e. g. through introduction of an ERP system for production operations. Depending on the complexity involved, this step requires fast feedback or control loops and adequate communication.

Monitoring and measuring

In step seven, processes are evaluated with the help of appropriate monitoring and measuring methods. These are necessary if technical or personnel risks or instabilities have been identified and, in particular, in cases involving risks related to customer requirements. Checking for possible indications of nonconformities with the target at an early stage is recommended, as a high level of measuring accuracy is of little use if results are only available too late.

Process improvement

In step 8, the data gained from process evaluation enable management to make a robust decision regarding the necessary improvement actions. As outlined above, the process approach of the ISO 9001 ensures a high level of transparency and thus supports organizations in launching and driving the improvement process in a targeted manner.

9 Context of the organization

The context of the organization is to bridge the gap from quality management to strategic management: What is the essential purpose of the organization? What are key external and internal influencing factors, and which interested parties have which claims and expectations relating to the products and services of the organization?

A quality management system according to ISO 9001:2015 must be familiar with the own organization, the external environment and the influencing factors which interact with the organization. This understanding can be generated by various analyses, such as competition analysis, trend analysis etc. These strategic management measures are management responsibilities.

The rationale of ISO 9001:2015 is that organizations need to consider their stakeholder's requirements in order to ensure sustainable success. Beyond customers, these can also include suppliers, owners, employees, authorities, business partners and even competitors.

Please note: Products or services need not meet the requirements and expectations of all external parties, but only of those considered relevant to the quality management system.



10 Risk-based thinking

The central requirements of risk-based thinking in ISO 9001:2015 show strong reference to strategic management. Now, the principle of prevention is present throughout the entire quality management system.

The standard defines opportunities as the result of a set of circumstances which follow from a situation and which impact favorably on achieving the intended results. For example, a situation may favorably impact on attracting new customers.

By contrast, risk is defined as the effect of uncertainty on an intended result, which is evaluated as negative.

ISO 9001:2015 examines all risks and opportunities in very direct connection to the processes in an organization. Therefore, the text of the standard also ensures clear differentiation from general risk management, e.g. as per ISO 31000.

In contrast to an extensive risk management system, quality management need not identify all risks existing in an organization, establish consistent evaluation and reporting, or take financial precautions, for example.

ISO 9001:2015 combines the analysis and evaluation of risks – and opportunities – right from the stage of process definition or revision. When planning for the quality management system, we must also examine the risks and opportunities to ensure that we will achieve the intended outputs and avoid undesirable results. However, not all processes of an organization involve the same level of risk. Given this, responsibility for risk-based thinking and the actions associated therewith rests with the organization. Organizations also can decide which risks to address, including whether or not to retain documented information as evidence of their determination of risks and opportunities.

The actions taken to address risks and opportunities shall be proportionate to their possible consequences.





11 Documented information

The new ISO 9001:2015 strengthens the responsibility of the organization. The organization itself is now responsible for determining what needs to be retained (how and for how long). Where the standard refers to “information” and not “documented information,” the organization can decide whether it wants to document this information or not.

The standard requires neither a quality management manual or documented procedures. Even if ISO 9001:2015 requires documented information at some points, the amount of documentation depends on the size of the organization, the complexity of its processes, the competence of persons and risks, etc.

ISO 9001:2015 gives organizations more flexibility regarding process documentation as a part of the management system. This applies to the documentation of management, strategy, and core processes as well as support processes – i.e. all processes within the organization. Generally, traceable documentation in forms such as a checklist or an electronic workflow will be required to provide guidance for defined work steps. However, this can be decided independently by the organization.

Also essential is that the organization addresses the aspect of control of documented information with respect to access, protection, storage and preservation, retrievability, identification, revision status etc. Annex 2 includes a table that summarizes the points at which ISO 9001:2015 requires documented information.

12 Handling of organizational knowledge

What knowledge is required for which process? Is the required knowledge available in the organization, or does it still need to be acquired? Building on these questions, organizations can determine their knowledge needs and derive possible fields of action. ISO 9001:2015 understands knowledge as an internal resource which needs to be controlled to ensure product and service conformity. Given this, it is essential for organizations to develop awareness of organizational knowledge as a resource across all levels of the organization. Knowledge is a tool to ensure successful corporate management. It must be sensibly applied to achieve the intended results.

No formalized knowledge management is required.



PART 2 – standard requirements of ISO 9001:2015

4 Context of the organization

This clause requires the organization to address

- external and
- internal issues that
- impact on its scope, its strategic direction, and
- its ability to achieve the intended results of its quality management system (QMS). (4.1.)

This includes

- understanding the requirements and expectations of interested parties (4.2);
- determining the scope of the quality management system (4.3), and
- its processes (4.4).

4.1 Understanding the organization and its context

Summary/interpretation:

Identification of (internal and external) issues which impact on the results of the QMS and are therefore important for the organization. Information about these issues must be monitored and evaluated.

Additional notes:

- Basic requirement is that the organization has verifiable knowledge of the requirements of the standard.
- Top management of the organization must be familiar with the purpose of the organization and its strategic

direction and able to explain the fundamental long-term strategy.

- Top management must have addressed the context of the organization (e.g. within the scope of management review).
- To audit the context of the organization, auditors require business-specific knowledge and understanding of the financial situation.
- Documented information of the context of the organization is advisable. However, verbal information is also possible (e.g. in case of small-sized organizations).

The organization must:

- Determine external and internal issues that are relevant for its purpose and strategic direction, e.g.
 - legal
 - cultural
 - competitive
 - social
 - economic
 - technological issues
- Determine and monitor the impacts/requirements (risks and opportunities) of these factors on
 - organization
 - products and services
 - investments
 - interested parties



Examples of audit questions:

- To what extent has the QMS resulted in competitive advantages (quality, on-time delivery, price), improved image, or higher customer benefits?
- What further positive effects, such as improvement of quality, are evident or achievable in the organization?
- What quality factors directly impact on the activities of the organization?
- What legal requirements that impact on financial and human resources are relevant for the organization?
- What risks and opportunities were determined for the context of the organization?

Examples of process evidence:

- Context of the organization
- Process description
- Interview with top management
- Management review
- Analysis of statutory and regulatory requirements
- STEP (social, technological, economic and political) analysis
- Strategy
- Scope of the QMS
- Business plans
- Benchmarking
- Mind mapping



4.2 Understanding the needs and expectations of interested parties

Summary/interpretation:

Identification of the interested parties that are relevant to the QMS and monitoring and review of information about those interested parties.

Additional notes:

- Interested parties comprise only those which are relevant to the organization's QMS.
- Interested parties (stakeholders) may include:
 - Internal:
 - Employees
 - Works council
 - Holding
 - Various representatives
 - External:
 - Competitors
 - Residents
 - Government/authorities
 - Trade unions
 - Associations
 - Investors/stakeholders
 - Customers
- The organization decides the extent to which interested parties are of relevance to the QMS.
- Top management of the organization must be able to provide information on this issue.
- Generally, documented information as evidence of the relevant interested parties is advisable. However, verbal information is also possible (e.g. in case of small-sized organizations).

- Requirements and expectations (risks and opportunities) of interested parties must be regularly (define interval) identified, monitored and taken into account. Where identified as relevant, they shall be considered binding on the organization.

Examples of audit questions:

- What relevant interested parties has the organization identified and how?
- Does the organization determine the requirements of interested parties?
- How does the organization assess and consider the requirements in relevant processes?
- What specific requirements are defined by interested parties?
- How does the organization maintain contact/communicate with neighbors or the local community and which changes/actions result therefrom?
- How does the organization engage its employees in the QMS (e.g. via the Q circle)?
- How does the organization ensure that regulatory requirements are systematically addressed?
- Does the organization maintain a register of legal requirements and how is this register kept up to date?

Examples of process evidence:

- List of relevant interested parties and requirements
- Method of identification of the needs and expectations of interested parties
- 360° analysis
- Stakeholder mapping
- Scope of QMS
- Register of legal requirements



4.3 Determining the scope of the quality management system

Summary/interpretation:

Determination of the scope of the QMS (type of products and services covered by the QMS).

The organization must apply all applicable requirements of the standard.

The organization must provide justification for any requirement of the standard that it deems non-applicable. Non-applicability of a requirement must not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.



Additional notes:

- The scope (sites/range of services) must be available in the form of documented information.
- Generally, the scope of the QMS must be described in more detail than the scope written on the certificate.
- The scope must cover all activities, products or services and equipment that significantly impact, or can significantly impact, quality.
- The scope must be defined on the basis of external and internal issues (4.1), the requirements of the relevant interested parties (4.2) and products and services.
- Exclusions from the scope (requirements of the standard that are not applicable) are only possible under certain conditions. Documented justification must be provided (e.g. non-application of monitoring and measuring equipment at a beverage bottling facility is unacceptable). Conversely, this means that justification must show how the organization manages to produce conforming products and services and improve customer satisfaction without applying this clause/these clauses. If the major part of design and development is performed by an external provider, the organization must prove that it has substantial control of the design and development process.

- Purchasing cannot be excluded for an entire organization. However, within the scope of multi-site certification (organization with more than one location), the non-applicability of purchasing at some locations may be possible.
- Outsourced processes and their interfaces with the organization, including control of these processes, must be defined.
- In organizations with multiple locations, the central QMS function must be entitled to require all locations to implement the actions that it considers necessary (control and influence).
- If an organization maintains several management systems, the independent objectives of the individual MS, if any, may have to be taken into consideration.

Examples of audit questions:

- What is the scope of the management system?
- How has the organization defined the boundaries of the scope?
- Which requirements of the standard has the organization defined as not applicable?
- How does the organization communicate the scope to interested third parties (e.g. customers)?

Examples of process evidence:

- Boundaries and applicability of the QMS
- Statement regarding the suitability of the scope
- Limitations of the scope
- Justification for non-application of requirements
- Scope verification
- Process landscape
- Organizational chart
- Register of companies

Explanation:



Documented information must be available

4.4 Quality management system and its processes

Summary/interpretation:

QMS structure, maintenance and continual improvement, identification of the necessary processes and their interactions.



Additional notes:

The organization needs to document its processes. The following aspects must be defined for all processes:

- Inputs and outputs of each established process
- Sequence and interaction (interfaces) of these processes
- Measurement of key performance indicators (KPIs)
- Resources needed and how to ensure their availability
- Assigned responsibilities
- Monitoring and measuring and continual improvement (CIP)
- Documented information that supports the implementation of processes must be available to the required extent.
- Evidence that processes are carried out as planned must be available.
- The type of process presentation is at the discretion of the organization, e.g. Turtle Model, flow chart, etc.
- The risks and opportunities of each process of an organization's QMS must be addressed. The organization determines how to define documented information of risks and opportunities and their relation to processes.
- For processes that do not form part of the core processes of a QMS (e.g. sales, design &

development, production, packaging, customer service) any decision as to whether there are risks that may impact on the conformity of products, services, and customer satisfaction is at the discretion of the organization. However, the organization must provide reasonable justification of its decision. The actions (see 6.1) to address risks and opportunities must be integrated into, and implemented in, the QMS processes.

- The organization must determine, apply, and analyze key performance indicators (KPIs) for all QMS processes (clause 10 – Improvement)
- The requirements for the quality management system must be integrated into the business processes.
- Processes within the scope (see 4.3) can be outsourced. The organization must be able to explain which processes have been outsourced.

Examples of audit questions:

- How are the management system processes and their interactions defined (approach)?
- How do the processes influence each other?
- How are the processes mapped?
- How are processes communicated within the organization?
- How are processes monitored?
- Are there any outsourced processes and which ones are they?

Examples of process evidence:

- Process landscape
- Process sheets (Turtle, ERP)
- Quality management manual
- Process flowchart
- Software-supported process mapping



5 Leadership and commitment

This clause is dedicated to

- the responsibilities and duties of management (5.1),
- its customer focus (5.2),
- the quality policy and its implementation (5.2) and the question of
- which roles, responsibilities and authorities are in place in the organization (5.3).

5.1 Leadership and commitment

5.1.1 General

Summary/interpretation:

Top management is responsible for leadership with respect to the QMS. Given this, top management is responsible for:

- accepting accountability for effectiveness
- establishing the quality policy and quality objectives and their compatibility with the context and strategic direction of the organization
- integrating the QMS requirements into the business processes of the organization
- process approach/risk-based thinking
- ensuring the availability of resources
- communicating the importance of the QMS
- ensuring achievement of the intended results
- improvements
- supporting employees and executives

Additional notes:

- Top management is responsible for the QMS and its effectiveness, and must demonstrate this by management reviews and other measures.
- Top management is responsible for promoting awareness of the process approach and risk-based thinking.
- Top management must ensure that the organization identifies risks and opportunities that impact on the conformity of products and services and on customer satisfaction.
- Top management (or a representative) must be available for the audit. A representative may only fill in during the audit in exceptional cases (for urgent

business reasons). However, that representative should be an employee of the company who can answer the auditor's questions, not an external consultant.

- Top management must be able to explain the context, quality policy and key aspects of the quality objectives of the organization.
- Top management is responsible for ensuring communication of customer requirements, the applicable legal requirements and regulations throughout the organization.

Examples of audit questions:

- How does top management fulfill their commitment?
- How does the organization develop the quality policy and quality objectives (including inputs)?
- Why is a QMS of strategic significance for the organization (e.g. market or customer requirements, targets)?
- How does top management ensure consistent internal communication of leadership issues?
- How does the organization communicate quality objectives across various levels of hierarchy (e.g. employee performance appraisals, KPIs, incentives for CIP)?

Examples of process evidence:

- Management review
- Works agreement
- Employee information (notices, agenda of information events)
- Quality policy
- Quality objectives
- Context of the organization
- Process flowchart
- Investment plan
- Qualification matrix
- Project plan
- Letter of undertaking
- Authorization matrix
- Strategy
- Action list

5.1.2 Customer focus

Summary/interpretation:

- Fulfillment of customer requirements and applicable statutory/regulatory requirements
- Identification of risks and opportunities and
- improvement of customer satisfaction

Additional notes:

Management is responsible for ensuring that customer requirements, applicable statutory requirements and regulations that are relevant for the quality of products and services have been established and fulfilled throughout the organization.

Examples of audit questions:

- What do customers demand from the organization's products/services?
- What does the organization do to improve customer satisfaction?
- How does top management fulfill their commitment with respect to customer focus?
- How does the organization take customer requirements into account in their products and services?

Examples of process evidence:

- Evaluation of customer surveys
- Market analysis
- Customer-satisfaction analysis
- Customer complaint report/analysis
- Evidence of compliance with statutory and regulatory requirements or conditions
- Performance specifications/requirements specifications



5.2 Policy

5.2.1 Establishing the quality policy

5.2.2 Communicating the quality policy

Summary/interpretation:

The quality policy must be established and implemented. It is documented, communicated within the organization, available to interested parties and includes commitments to satisfy the applicable requirements and engage in the continual improvement of the QMS.



Additional notes:

- The quality policy must be available as documented information, communicated within the organization and be available to the relevant interested parties.
- Posting the quality policy on a notice-board or uploading it to the Intranet is not sufficient.
- The linking of quality policy, context, scope of the QMS, (key) performance indicators and quality objectives must be evident and traceable.
- Conformity with the strategic direction and context of the organization (i.e. with clause 4) must be evident.

Examples of audit questions:

- When did the organization last review its quality policy for appropriateness and what were the results?
- Which criteria does the organization use to assess the appropriateness of its quality policy?
- How does the organization communicate its quality policy within the organization?

Examples of process evidence:

- Quality policy
- Context of the organization
- Internal audit report
- Management review
- Corporate strategy and principles
- Relevant interested parties
- Quality objectives
- Communications to employees (black board, notices, Intranet etc.)

5.3 Organizational roles, responsibilities and authorities in the organization

Summary/interpretation:

Assignment of roles, responsibilities and authorities must be traceable and understandable. It must ensure achievement of the intended results of the QMS.



Additional notes:

- To ensure that the assignment of roles, responsibilities and authorities is traceable, these must generally be available as documented information.
- ISO 9001:2015 does not explicitly require quality management representative. However, organizations can still define and delegate this function.
- The responsibility of top management is strengthened and expanded (e.g. definition of the strategic direction). It must demonstrate clear commitment to the QMS.

Examples of audit questions:

- What roles, responsibilities and authorities has the organization defined as relevant for its QMS?
- How does the organization communicate responsibilities within the organization?
- On what basis/according to which requirements does the organization define its functions?

Examples of process evidence:

- Assignment of roles, responsibilities and authorities
- Job/functional profile
- Organizational chart
- Letter of appointment of QM representative
- Process landscape or process map
- Signature authorization
- Deputization arrangements
- Employment contracts
- HR development plan
- Delegation of responsibilities

6 Planning

This clause defines the requirements for the organization's planning systems and

- the actions to address risks and opportunities (6.1),
- quality objectives and planning to achieve them (6.2), and
- the planning of changes (6.3).

6.1 Actions to address risks and opportunities

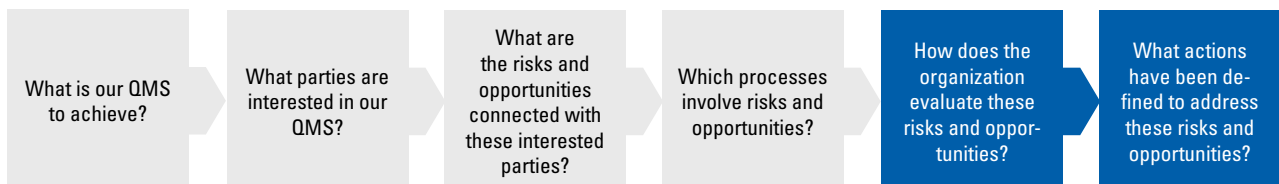
Summary/interpretation:

When planning the QMS, organizations must identify the risks and opportunities that need to be addressed to achieve the intended results.

Additional notes:

- Risks constitute the positive and negative effects of uncertainty regarding an expected result (ISO 9000:2015).
- ISO 9001:2015 does not require formal risk management (e.g. ISO 31000).
- One of the core purposes of the QMS is to act as a preventive tool. The risk-based approach must already be considered during formulation of QMS requirements
- Risks and opportunities must be determined and must result in actions. However, these actions must be in proportion to the potential damage.

- Examples of opportunities:
 - Opening of a market niche or access to new markets (e.g. based on bilateral agreements)
 - Reduction of reject rates or rework
- Examples of risks:
 - Difficulties during the ramp-up phase of new products
 - Demographic challenges
 - Data security (e.g. in purchasing, personnel, warehousing, supply chain etc.)
 - Shorter product cycles (innovation pressure)
- References to risks and opportunities can be found in clause 6.1 and many other clauses of ISO 9001:2015, e.g. 4.2 (Interested parties), 5.1.2 (Customer focus) or 9.3.1 (Analysis and evaluation).
- Risk-based thinking ensures that risk is taken into account from the outset and throughout the process approach. Risks are frequently only regarded as negative.
- However, risk-based thinking may also help to identify opportunities. This can be seen as the positive side of a risk.



Examples of audit questions:

- What systematic method has the organization applied to determine and analyze risks and opportunities?
- Which systematic method has the organization applied to define actions for risks and opportunities?
- How has the organization evaluated the effectiveness of the defined measures?
- How has the organization considered the context and the interested parties in its planning of actions to address risks and opportunities?
- How does the organization explain cases in which it did not define any actions to address risks and opportunities?
- Which type of cyber security threats (data security) has the organization identified, and how does it handle these threats?

Examples of process evidence:

- Definition of risks and opportunities
- Risk matrix
- Action list
- Risk analysis (FMEA, SWOT)
- Context of the organization
- Relevant interested parties
- Process description for risks and opportunities;
- Cost/benefit analysis for projects
- Risk management (risk map, risk product map)
- Penetration test (data security)



6.2 Quality objectives and planning to achieve them

Summary/interpretation:

Establishment of the quality objectives at relevant functions, levels and processes needed for the QMS.



Additional notes:

- Documented information of the quality objectives and records of achievement of the objectives must be available.
- Quality objectives must have a connection to the quality policy, be relevant to conformity of products and services and to enhancement of customer satisfaction, and include the identified risks and opportunities (the central theme must be consistent and traceable).
- Quality objectives must be measurable (SMART – specific, measurable, attainable, realistic, time-bound)

Examples of audit questions:

- To what extent are the organization's quality objectives consistent with the quality policy?
- How does the organization communicate its quality objectives?
- How does the organization evaluate achievement of the quality objectives?
- How does the organization ensure that it achieves the quality objectives it has set itself?

Examples of process evidence:

- Quality objectives
- Quality plan
- Internal/external target agreements (business plans, project plans, quality assurance agreements)
- Trend analysis

6.3 Planning of changes

Summary/interpretation:

Should changes to the QMS become necessary, these changes must be carried out in a planned manner.

Additional notes:

- Changes to the QMS are only acceptable if based on systematic planning and implementation.

Examples of audit questions:

- How does the organization plan and control changes?
- How has the organization evaluated the purpose and benefits of the changes?
- How do the changes impact on the QMS?
- How does the organization determine the necessary resources in case of changes to the QMS?
- What aspects that impact on changes to the MS does the organization take into account, e.g.: context?

Examples of process evidence:

- Documented procedure
- Project plan
- Milestone plan
- Project development plan
- Change project

7 Support

This clause outlines the requirements regarding the resources needed for QMS establishment and maintenance.

They include:

- Resources, people, infrastructure, process operation environment, monitoring and measuring resources and organizational knowledge (7.1)
- Employees' competence (7.2) and awareness of the QMS (7.3)
- Communication of the organization (7.4)
- Requirements for documented information (7.5)

7.1 Resources

7.1.1 General

Summary/interpretation:

The organization must determine and provide the resources needed for establishment, implementation, maintenance and continual improvement of the QMS.

Additional notes:

- The resources needed for the QMS must be regarded in relation to the organization's economic situation.
- The necessary resources should be in relation to the scope of the QMS, quality policy, processes, objectives and size of the organization.

Examples of audit questions:

- What system has the organization applied for internal determination of the resources needed for the QMS?
- How does the organization continually verify which resources are needed for the QMS?
- How does the organization prioritize the necessary investments in new resources (e.g. state of the art)?
- How has the organization included contingency planning in resource planning?

Examples of process evidence:

- Resource planning (e.g. investment plan, budget plan)
- Records of process capability analysis
- Records of supplier evaluation (including service providers)

7.1.2 People

Summary/interpretation:

The organization must determine the persons necessary for effective implementation of its QMS.

Additional notes:

- Risk-based thinking should be considered when determining the persons necessary for the QMS.
- Persons responsible and employees should be clearly assigned to the established processes (see 4.4.)
- If an organization uses temporary/leased staff, these employees must also receive induction and continual training.
- The age structure in the organization should be considered and analyzed.

Examples of audit questions:

- How has the organization addressed demographic change?
- How has the organization determined systematically which persons are needed for the QMS?
- How has the organization determined the workload of its personnel?
- How does the organization ensure that temporary staff/leased personnel (continually) meet its requirements?

Examples of process evidence:

- Job/HR planning
- Investment plan for employees
- Duty roster
- Job description
- Qualification matrix
- Training records

7.1.3 Infrastructure

Summary/interpretation:

The organization must determine and provide the necessary infrastructure to maintain conformity of products and services.

Additional notes:

- Infrastructure can significantly influence the quality of products and services.
- The organization not only needs to define the necessary infrastructure (determine what is needed), but must also monitor and control the interfaces with purchasing (procurement) and maintenance (servicing). Given this, these requirements are mostly spread across several processes.

Examples of audit questions:

- What is the state of repair of the organization's infrastructure (including hardware and software)?
- What large-scale investments in infrastructure has the organization made in the last year and/or are currently being planned/implemented?
- How does the organization determine necessary investments in infrastructure?

Examples of process evidence:

- Investment plan for buildings and associated building technologies
- Technical equipment, including hardware and software
- Transport facilities
- Information and communication technology
- Investment plan for equipment and real estate
- Maintenance plan
- Internet, intranet, extranet
- Overview of maintenance costs

7.1.4 Environment for the operation of processes

Summary/interpretation:

Determination of the environment necessary to achieve conformity.

Additional notes:

- Compliance with this requirement of the standard should be checked within the scope of the on-site inspection and the on-site audit

Examples of audit questions:

- What are the value adding processes of the organization?
- What criteria did the organization consider when designing the environment for the operation of processes?
- What regulatory and statutory requirements did the organization consider when planning the environment for the operation of processes?

Examples of process evidence:

- Process environment (orderliness, noise, temperature, humidity, cleanliness, lighting, etc.)
- Workplace studies
- Work environment related statutory and regulatory requirements
- Maintenance/servicing schedule (records)
- Work environment benchmarking

7.1.5 Monitoring and measuring resources

7.1.5.1 General

7.1.5.2 Measurement traceability

Summary/interpretation:

Determination and provision of the resources needed for suitable monitoring/measuring to verify the conformity of products and services to requirements. The necessary measuring equipment must be suitable and calibrated/verified.



Additional notes:

- The organization must maintain documented information as evidence of the resources' fitness of purpose.
- If no standard exists, the basis of calibration or verification must be available.
- Identification of the monitoring and measuring equipment should be checked within the scope of the on-site inspection or the on-site audit.
- While in the past this clause referred primarily to technical measuring equipment, the heading now includes anything that may contribute to measuring or monitoring, i.e. also checklists or questionnaires.
- Requirements for measuring quality or the validity and suitability of measuring equipment do not differentiate between production and service provision.
- Reference to a standard can be waived in certain cases, even if measurements of relevance for quality are performed.

Examples of audit questions:

- What monitoring and measuring equipment does the organization use to monitor the conformity of products and services?
- What documented information is available as evidence of calibration of monitoring and measuring equipment?
- How does the organization ensure that monitoring and measuring equipment is suitable for measurement?

Examples of process evidence:

- Documented information as evidence of the conformity of products and services, including defined requirements
- Test record/certificate, including acceptance criteria
- Evidence of the capability of monitoring and measuring equipment
- List/file index of test equipment/management of software programs
- Calibration instruction
- Certificate/record of calibration
- Records of software capability test
- Initial sample test report
- Records of sensory tests (visual, taste, odor)

7.1.6 Organizational knowledge**Summary/interpretation:**

The organization must determine the knowledge necessary to achieve conformity of products and services with the defined requirements.

Additional notes:

- Knowledge comprises internal and external knowledge. The necessary knowledge shall be determined, maintained, and made available.
- The organization must consider its current knowledge compared against evident changes and determine how to acquire necessary additional knowledge.
- Examples of organizational knowledge:
 - Internal:
 - Intellectual property
 - Knowledge gained from experience
 - Lessons learned from projects
 - Capturing and sharing undocumented knowledge and experience
 - Succession policy
 - External:
 - Standards
 - Universities
 - Conferences
 - Trade shows
 - Gathering knowledge from customers

Examples of audit questions:

- How does the organization acquire knowledge?
- How does the organization protect current knowledge (e.g. succession policy)?
- How does the organization handle confidential knowledge (e.g. access rights, authorizations)?



Examples of process evidence:

- Sources forming the basis of organizational knowledge
- Work induction plan
- Qualification matrix
- Process landscape
- Technical specifications
- Certificate of competence
- Appointment of deputies
- Succession policy
- Non-disclosure agreement

7.2 Competence**Summary/interpretation:**

Employees need to be competent.

**Additional notes:**

- The organization must retain appropriate documented information as evidence of the competence of its employees.
- The competence of employees is verified at various instances, including during the auditing of other elements of the standard.
- Employees should be able to assess and present process effectiveness.
- Competence is the combination of ability, knowledge, and skills. Deficits, if any, must be eliminated by training, job rotation, mentoring, and other measures.

Examples of audit questions:

- How does the organization identify the competence requirements of its staff?
- How does the organization ensure compliance with the identified competence requirements (e.g. training, mentoring, exchange programs)?
- How does the organization determine and implement identified training needs?
- How does the organization evaluate the effectiveness of training measures and how does it handle non-achievement of training goals?
- How does the organization ensure that external employees (e.g. temporary staff/leased personnel) have the necessary competence?

Examples of process evidence:

- Qualification matrix
- Records of qualification requirements
- Job/functional description

- Employee development/training plan
- Documented information of evaluations of training effectiveness
- Documented information of evaluations of competence
- Records of employee appraisals/job reference
- Employment contract
- Induction plan

7.3 Awareness**Summary/interpretation:**

To meet the requirements of the QMS, employees must be aware of the quality policy and relevant quality objectives and of the implications of failing to conform with QMS requirements.

Additional notes:

- The organization should take appropriate actions to promote the awareness of QMS requirements of people not directly employed by the organization (e.g. service providers).
- Organizations must ensure that employees are aware of the significance of their activities and how they contribute to achievement of quality objectives, and/or of the consequences of not conforming to the requirements.

Examples of audit questions:

Aspects to include during employee interviews:

- How was the employee informed of the QMS?
- How does the QMS influence employees in their activities and what has changed since QMS establishment?
- To what extent are employees aware of the quality policy and quality objectives?
- What happens if people fail to observe rules and do not conform to requirements?
- What information do employees need for their activities and how does the organization handle access to this information?
- What contact partners are available, if necessary?

Examples of process evidence:

- Documented information of training on quality policy
- Documented information of training on relevant quality objectives
- Documented information of training on QMS
- Minutes of quality circle
- Quality workshop
- Employee performance appraisals

7.4 Communication

Summary/interpretation:

The organization must determine the type of internal and external communication.

Additional notes:

- Organizations should have reflected on “communication strategy” (both horizontal and vertical) and its implementation in the organization.
- The quality of communicated information is assessed in the audit.
- External communication needs may also concern relevant interested parties.

Examples of audit questions:

- How does the organization handle customer queries and complaints?
- How does the organization handle improvement suggestions?
- How does the communication strategy work within the organization?
- What regulations apply to external communication?

Examples of process evidence:

- Concerns by third parties/external communication
- Minutes and reports of meetings
- Website
- Product description
- Team training and other meetings
- Bulletin boards, internal publications and newsletters
- Audiovisual and electronic media (Intranet, notices, information boards).
- Agenda of company events
- Communication matrix/diagram
- Minutes
- Process description



7.5 Documented information

7.5.1 General

Summary/interpretation:

The organization must define the extent of documented information for the QMS, depending on the requirements of the standard and the information necessary for the organization and for QMS effectiveness.



Additional notes:

- The documented information required by the standard must be on hand.
- Documented information which the organization deems necessary for QMS effectiveness must be available.
- The requirements for documented information depend on the size, complexity and the risks of the organization.
- Flexible documentation offers particular advantages for the organization. This applies in particular to the establishment of a new QMS or restructuring of an existing system and to expansion of a QMS to include other management systems (e.g. environmental management, occupational

health and safety management).

- There are no explicit requirements for documented procedures or a QM Manual. This depends on the complexity of the organization's document structure.
- A document review is carried out (in stage 1, or in the case of major changes).
- During the audit, the audit team will make random checks to verify access to, and navigation in, electronic systems.
- During the audit, the audit team will make random checks to verify access to relevant documented information.

Examples of audit questions:

- How is the handling and control of documents defined in the organization?
- How are data security and retention defined in the organization?
- How does the organization ensure update (patch) management?

Example of process evidence:

- List/overview of documented information.



7.5.2 Creating and updating

Summary/interpretation:

The organization must define the identification and format of documented information and their review and approval.

Additional notes:

- During the audit, the audit team will carry out random checks of the identification, format and approval of documented information at their place of use.
- The organization should check whether internal/external documented information might be necessary in several languages (e.g. work instructions for employees with little or no knowledge of German; technical product specifications for international customers).

Examples of audit questions:

- How does the organization check the suitability of documented information?
- How does the organization review the content of documented information?

Examples of process evidence:

- Data management/data protection
- Retention period of revised documented information
- Revision and approval procedures

7.5.3 Control of documented information

Summary/interpretation:

The organization must control documented information to ensure the latest version is always available at the workplace. Confidentiality requirements must be observed.

Additional notes:



- The organization must have provisions on the control of documented information as evidence of conformity.
- The organization must retain documented information as evidence of conformity.
- The principles of distribution, access and use must be addressed.
- Control of changes (version control) and retention must be addressed.
- Measures taken to ensure data protection (e.g. restricted access authorization) must be addressed.

Examples of audit questions:

- How does the organization address external documented information?
- How does the organization protect documented information from unauthorized changes?
- How does the organization ensure the availability of documented information?
- How does the organization ensure that its documented information is up to date?

Examples of process evidence:

- Process/document procedure: Control of documented information
- Sales and order records
- Documented information from internal audits
- Procurement records
- Test certificates
- Production certificates
- Distribution keys and lists
- Process/document procedure: Control of electronic documented information
- Process/document procedure: Control of external documented information
- History of revisions

8 Operation

Requirements for the necessary planning/control of the processes needed to provide the products/services.

This includes:

- Planning of processes (8.1)
- Requirements for products and services (8.2)
- Design and development of products and services (8.3)
- Control of externally provided processes, products, and services (8.4)
- Production and service provision (8.5)
- Release of products and services (8.6), and, in case of nonconforming products/services,
- Management/control of nonconforming outputs (8.7)

8.1 Operational planning and control

Summary/interpretation:

The organization must plan, implement and control the processes needed to meet the requirements for products and services.



Additional notes:

- Documented information must be determined, maintained and retained to the extent necessary to allow confidence that the processes have been carried out as planned and to demonstrate that the conformity of products and services has been ensured.
- There must be higher-level planning in the organization and the organization's strategic direction must be available.
- The planning must consider and analyze target/performance comparison.
- The organization must determine concrete quality planning in conjunction with 4.4 (Processes) and 6.1 (Actions to address risks and opportunities).

Examples of audit questions:

- What is the strategic direction for the products/services?
- How does the organization ensure that operational planning is in conformity with the strategic direction?
- What processes are needed for operational planning and control?
- How does the organization control the relevant QMS processes?
- Does the organization maintain any outsourced processes, and if so, which?
- What production equipment/resources (including personnel) are in place?

Examples of process evidence:

- Manufacturing and production plan
- Definition of the required resources (layout plan etc.)
- Project development plan
- Process landscape
- Outsourced processes
- Milestone plan
- Measurement and test strategy
- Technical specifications
- Results of process and product quality
- Product/service portfolio
- Revenue/sales/budget planning
- Specification, drawing

8.2 Requirements for products and services

8.2.1 Customer communication

Summary/interpretation:

The organization must control customer communication within the context of the manufacturing of products and the provision of services.

Additional notes:

- The organization must control customer communication.
- “Emergency measures” must be added to customer communication if necessary.
- Every company must define and communicate requirements for emergency measures.

Examples of audit questions:

- What customer property is available in the organization?
- How does the organization handle customer property?
- How (media, methodology) does the organization communicate information about products/services to the outside?
- How does the organization handle enquiries/orders?
- What complaints did the organization receive last year?
- How is the management of change requests regulated and how does the organization handle change requests?

Examples of process evidence:

- Advertising material
- Enquiry document/processing
- Regulations regarding the handling of customer property and emergency measures, where appropriate
- Specific customer requirements
- Product specifications
- Handling of complaints
- Complaints
- Customers’ product specifications
- Confirmation of order
- Change request by the customer
- Complaints analysis
- Change of order

8.2.2 Determining the requirements for products and services

Summary/interpretation:

Determining the requirements for products and services.

Additional notes:

- Strong focus on the definition of requirements for products and services to facilitate the subsequent verification of this phase.

Examples of audit questions:

- What are the legal and official requirements for the product/service?
- Are there any requirements (legal or from customers) that cannot be met, and if so, what are they and why?

Examples of process evidence:

- Preparation/processing of offer quotation?
- Specifications
- Product relevant standards and statutory requirements
- Feasibility study

8.2.3 Review of the requirements for products and services

Summary/interpretation:

The organization must ensure that it is able to meet the requirements for products and services.



Additional notes:

- Documented information of the review results and of all new requirements for products and services must be retained (if applicable).
- The organization must always be able to fulfill promises made regarding products and services and knowledge of the intended use by the customer must be considered in the question of feasibility – even if not explicitly required by the customer.

Examples of audit questions:

- How does the organization review requirements for products/services (feasibility analysis)?
- How does the organization determine requirements for products/services not explicitly stated by the customer?
- How frequently does the organization review the requirements for products and services?

Examples of process evidence:

- Review of contract for customer requirements
- Compliance with requirements not specified by the customer
- Feasibility study
- Specifications
- Outcomes of review of requirements
- Confirmation of order
- Quotation/Offer, contract
- Legal requirements

8.2.4 Changes to requirements for products and services**Summary/interpretation:**

To meet requirements for products/services that may have changed, the organization must amend the relevant documented information and communicate the changes to the relevant employees.

Additional note: 

- Amendment of documented information must be ensured in case of changes of requirements for products and services.

Examples of audit questions:

- How does the organization identify, plan and control the necessary changes?
- What are the results/consequences and risks of unplanned/unintended changes (nonconformities of services, products)?
- Does the organization define actions in case of unintended changes and how does it monitor these actions?

Example of process evidence:

- Change management



8.3 Design and development of products and services

8.3.1 General

Summary/interpretation:

The design and development that may be necessary for production/service provision must first be prepared in an appropriate design and development process. The organization must implement and maintain this process.

Additional notes:

- Design and development of products and services is considered applicable if the organization defines and/or modifies the specification of products/ services itself.
- If the characteristics and information of products/ services are defined by customers or government/ the legislator, for example, clause 8.3 (or parts thereof) may be not applicable.
- If project management or process design and development do not impact on the products/ services of an organization clause 8.3 may not apply, at least partially.

Example of an audit question:

- What is a current/recently completed design and development project?

Examples of process evidence:

- Design and development project
- Pilot study
- Performance and requirements specifications
- Design and development process

8.3.2 Design and development planning

Summary/interpretation:

Design and development must be planned and framework conditions must have been defined.



Additional notes:

- The organization must maintain the required documented information to confirm the requirements for design and development.

Examples of audit questions:

- What are the phases for design and development projects of the organization? What is a current design and development project and in which development phase is it currently in?
- Which requirements does the organization impose on its design and development process?
- How does the organization determine the necessary resources for a design and development project?

Examples of process evidence:

- Documented information that the organization meets the design and development requirements
- Project and resource plan
- Flowchart
- Feasibility study
- Milestone plan
- Measuring and test plan
- Verification and validation requirements
- Risk assessment



8.3.3 Design and development inputs

Summary/interpretation:

The organization must determine the requirements and information that find their way into the design and development process.

Additional notes:

- The organization must retain documented information of design and development inputs.
- The inputs for design and development must be clear and complete and in compliance with product/service characteristics.
- When determining inputs, the organization must take into account various aspects, including the required function and performance of the product or service, possible risks and subsequent damage arising from nonconforming products/services.

Examples of audit questions:

- To what extent does the organization take lessons learned from previous design and development projects into consideration for the planning and implementation of a new project?
- What inputs does a design and development project need to be effectively implemented?
- What possible risks has the organization considered in the design and development project?

Examples of process evidence:

- Evidence of design and development inputs
- Legal requirements, standards, state of the technology
- Lessons learned/experience from previous projects
 - Technical specifications
 - Patent investigation
 - Release documentation

8.3.4 Design and development controls

Summary/interpretation:

The design and development process must be planned and controlled.

Additional notes:

- The organization must maintain documented information of the activities to control the design and development process.
- Organizations must make sure to take note of the difference between verification and validation activities. Verification covers a technical review

of the requirements. Validation means that outputs are tested in the specified application (for the customer).

Examples of audit questions:

- How does the organization check whether the outputs of design and development meet the project requirements?
- How does the organization verify and validate the conformity with these requirements?
- Which nonconformities did the organization identify during verification/validation and how did it handle them?

Examples of process evidence:

- Documented information of the continuous control of a design and development project
- Test plan (validation requirements)
- Laboratory test
- Results of pilot series/field testing
- Test records/reports (also from customers, where applicable)
- Validation approval
- Prototypes/test samples
- Milestone and gate reviews
- Design and development/interim/final reports
- FMEA

8.3.5 Design and development outputs

Summary/interpretation:

Design and development outputs must demonstrate that the requirements for products/services are met and that production processes are adequate for providing products/services in the requested quality.

Additional notes:

- The organization must maintain documented information on design and development outputs.
- Design and development outputs should meet the input requirements.
- Design and development outputs are inputs for production/service provision. In this context, ISO 9001:2015 does not differentiate between internal and outsourced processes.
- Design and development outputs should supply exact requirements for the subsequent monitoring and measuring of processes, products, or services and for subsequent acceptance.

Examples of audit questions:

- What design and development outputs does the organization pass on and to which processes?
- How does the organization ensure understandable and appropriate communication of design and development outputs for further processes?
- How does the organization consider design and development outputs in test plans?

Examples of process evidence:

- Verification and validation meetings
- Design and development report
- Release documents and test records
- Evidence of design and development outputs
- Drawing
- Order specification document
- Test records (for production, verification and validation)
- Confirmation of acceptance

8.3.6 Design and development changes**Summary/interpretation:**

The organization must implement the necessary changes made during or after design and development under controlled conditions.

**Additional notes:**

- The organization must retain documented information on design and development changes, results of reviews, the authorization of changes and the actions initiated to prevent adverse impacts.
- The documented information should show who approved the changes, which processes are affected by the changes and how the changes are communicated.
- The design and development process should consider the interactions with other processes/ areas/interested parties. This can result in possible design and development changes.

Examples of audit questions:

- Which changes to design and development projects were effected?
- How does the organization assess the impacts of changes to design and development processes?
- What risks and opportunities have resulted from these changes?

Examples of process evidence:

- Documented information of design and development changes
- New revision status of technical specifications, drawings, process descriptions, test procedures, monitoring and measuring equipment etc.
- Test report of design changes
- Acceptance documents on completed changes
- Risks and opportunities
- Action list

8.4 Control of externally provided processes, products, and services**8.4.1 General****Summary/interpretation:**

The organization must ensure that externally provided processes, products and services conform to requirements and must determine the controls to be applied.

**Additional notes:**

- The organization must retain documented information on the following activities: results of evaluation, selection, monitoring of performance and re-evaluation of external providers and all necessary actions.
- The organization must retain the following documented information on outsourced processes, depending on their influence on quality (risk assessment!): description of interfaces, e.g. in agreements concluded with the relevant contractors and providers, must be available, referencing process descriptions and work instructions if necessary, etc.
- The standard requirement no longer focuses solely on the qualification and evaluation of suppliers, but is expanded to include all external providers that impact on product and service quality.
- The assessment now covers the entire external value chain.
- The standard differentiates between providers, whose components are incorporated into the organization's products (direct providers (third parties in a contract)), and providers of outsourced processes. Overlapping is possible.
- In this context it is important to assess the potential impacts of externally provided processes, products and services on the products/services of the organization.

- The extent of the control activities is determined by the risk-based thinking on which the standard is based.

Examples of audit questions:

- Does the organization have outsourced processes, and if so, how does it ensure the safety and reliability of these processes?
- How does the organization control outsourced processes?
- How does the organization communicate requirements to external providers?
- How does the organization procure external products/services?
- What legal requirements are applicable (product, service)?

- What criteria are available for selection, assessment, and evaluation/development of new and existing providers?
- Does the organization maintain a classification/ grouping of suppliers (e.g. revenue, risk assessment, strategy and competition)?

Examples of process evidence:

- Documented information of control of the quality of outsourced processes, products and services
- List of approved suppliers
- Quality agreement/contract
- Supplier evaluation
- Supplier classification
- Supplier audit
- Evaluation criteria



8.4.2 Type and extent of control

Summary/interpretation:

The type and extent of control must be defined.
The objective is to deliver conforming products and services to customers.

Additional notes:

- Outsourced processes can be monitored via defined key performance indicators (KPIs), e.g. monitoring of deadlines, quality and delivery conditions.
- Supplier audits may prove useful to control implementation.

Examples of audit questions:

- How does the organization evaluate and monitor the requirements for externally provided processes?
- What are the type and extent of controls and potential impacts of externally provided processes and how does the organization determine them?
- How does the organization verify the results of external processes?

Examples of process evidence:

- Contractual regulations, taking into account legal and regulatory requirements
- First article inspection
- Inspection of incoming goods/acceptance of goods
- Product specification, including verification and validation requirements
- Regulations regarding outsourced processes
- Suppliers' test records
- Supplier audits
- Missing parts list

8.4.3 Information for external providers

Summary/interpretation:

The organization must control its communication with external providers.

Additional notes:

- The organization must regulate and clearly communicate the requirements for products and services of external providers and their controls.
- The organization's information to external providers should be checked. This can be done simply on the basis of a checklist, the four-eye principle (principle of dual control), or even a telephone confirmation.
- The information to external suppliers should cover all relevant criteria for the product/service, such as technical characteristics, types of tools, packaging, identification, laboratory analyses, test records etc.
- External providers must be monitored. How the organization manages such monitoring shall be communicated to the provider (e.g. supplier audits).

Examples of audit questions:

- Which requirements related to the product/service and its measurement were communicated to external providers and how?
- How do external providers ensure that they meet the requirements for the product/service?
- How does the organization monitor the service of the external supplier?

Examples of process evidence:

- Supplier audit
- Product specification (including approval of methods, processes or equipment)
- Evidence of personnel qualification
- Order specification document
- Order list, piece list
- Service level agreement/delivery contract
- Quality assurance agreement

8.5 Production and service provision

8.5.1 Control of production and service provision

Summary/interpretation:

The organization must implement production and service provision under controlled conditions.

Additional notes:



- The organization must maintain documented information on the characteristics of the products to be produced/services to be provided and the outcomes to be achieved.
- Actions taken to prevent human error depend on the complexity and the risk associated therewith and can extend from e.g. instructions or inductions about the 4-eye principle (principle of dual control) to control plans and poka-yoke.

Examples of audit questions:

- How does the organization implement the requirements from operational planning in production/service provision?
- How does the organization identify and monitor the acceptance criteria for products/services?
- Which actions to prevent human error does the organization implement and how does it verify their effectiveness?

Examples of process evidence:

- Machine and process capability records
- Process monitoring data
- Work plan including manufacturing steps
- Data of machine setting
- Process validation
- Product specification, including verification and validation requirements
- Verification and validation of manufacturing processes
- Suitable infrastructure and process environment
- Process description
- Installation plan
- Control plan
- Qualification matrix
- Action list
- Manufacturing and production plan
- List of orders
- Poka-yoke
- 4-eye principle (principle of dual control)



8.5.2 Identification and traceability

Summary/interpretation:

The processes of an organization must be implemented under controlled conditions, i.e. the organization must apply suitable means to identify the outputs necessary for its products and services.



Additional notes:

- The organization shall maintain documented information that enables traceability.
- Organizations define how identification and traceability must be applied. They need to determine why something should be, or has to be, identified (e.g. legal requirements) and in which process.
- In case of recalls, complaints, or, for example, cases of liability, documented information as evidence of identification will be necessary to protect the organization from heavy financial penalties. One example concerns the traceability of monitoring measuring equipment and their regular calibration.
- The type of identification depends on the output. Examples of identification and traceability can include:
 - Order number
 - Parts number(s)
 - Label, inscription or marking
 - Barcode (electronic)
 - Checklist, including service number

Examples of audit questions:

- To what extent is traceability required/necessary for the products/services of the organization?
- Using an example, how can the organization prove traceability?
- In what cases did the organization apply traceability in the last year or did traceability prove helpful?

Examples of process evidence:

- Accompanying document, routing slip
- IT records
- Test certificates
- Work instructions
- Product identification
- Segregation slip

8.5.3 Property belonging to customers or external providers

Summary/interpretation:

The organization must regulate the handling of external property.



Additional notes:

- The organization must retain documented information if property of customers or external providers is lost, damaged etc.
- The auditor must check the identification of customer property against the internal requirements of the organization.

Examples of audit questions:

- Which customer property is currently present in the organization?
- How does the organization ensure that customer property is not damaged?
- Did the organization damage customer property in the last year, and if so, what?
- What does the organization define as customer property?

Examples of process evidence:

- Inventory of customer property
- Identification (labels, engraving, inventory, etc.) of customer property
- Contractual regulations regarding the property of customers or external providers
- Instructions on the handling of damaged property of customers or external providers
- Incoming goods inspection
- Evidence about loss or damage of customer property

8.5.4 Preservation

Summary/interpretation:

The organization must preserve the outputs of production and service provision to the extent necessary to ensure conformity to requirements.

Additional notes:

- The organization must identify the process outputs that may deteriorate in quality over time and determine the extent and impacts of such deterioration in quality. The organization must address this by taking appropriate counteractions.
- Preservation of outputs not only refers to the finished product or service, but also to the results of the individual processes. This includes mounting parts, components and even information.
- The quality of products/services may be impaired during handling or storage, e.g. from one production line to the next. Organizations must be able to identify this and take appropriate counteractions.

Examples of audit questions:

- Which process outputs can deteriorate over time and how?
- How does the organization ensure that the quality of outputs is maintained and does not deteriorate?
- From when and under which conditions does the quality of products/services deteriorate?

Examples of process evidence:

- Packaging, preservation and delivery regulations
- Inventory data/lists
- Regulations on storage periods and segregation, where appropriate
- Accompanying documents/dispatch labels
- Packaging specifications
- Technical specifications

8.5.5 Post-delivery activities

Summary/interpretation:

Identification of the post-delivery activities necessary for the provision of products/services.

Additional notes:

Examples of post-delivery activities

- Warranties and guarantees
- Disposal of old products/packaging (during mounting/assembly on-site at the customer)
- Technical support

Examples of audit questions:

- Which statutory and regulatory requirements apply to product or services after delivery?
- Which further services does the organization offer after delivery?
- What customer requests/requirements apply to the product/service after delivery?

Examples of process evidence:

- Contractual regulations on warranty, maintenance/ servicing
- Additional services (e.g. recycling or disposal)
- Order documentation/work plan/route cards
- Operating instructions/user manuals
- Statutory and regulatory requirements

8.5.6 Control of changes

Summary/interpretation:

The organization must review, control and document the necessary changes in production or service provision.

Additional notes:



- The organization must retain documented information of the results of the review of changes, including the names of the person(s) authorizing said changes and any necessary activities arising from the review.
- Changes during production/service provision can become inputs for the design and development process (8.3.3).
- Changes can be based on internal or external reasons.
- The necessary changes must be reviewed prior to implementation in all processes concerned.

Examples of audit questions:

- How does the organization identify, plan and control the necessary changes?
- What are the results/consequences and risks of unplanned/unintended changes (nonconformity; service, product, process)?
- Does the organization define actions in case of unintended changes and how does it monitor these actions?

Examples of process evidence:

- Changes in production and service provision
- Results of the review of changes
- Minutes of meetings
- Training records
- Revised work instructions



8.6 Release of products and services

Summary/interpretation:

The organization must carry out checks at appropriate stages in the process to verify that the requirements for the products and services have been met.

Additional notes:



- The organization must retain documented information about the release of products and services, including evidence of conformity with the acceptance criteria and traceability to the persons authorizing the release.
- Products and services must not be released to customers until all individual criteria have been fulfilled completely.
- Traceability to the persons authorizing release must be ensured.

Examples of audit questions:

- Did the organization fail to fulfill the intended requirements for some products/services, and, if so, what was the nonconformity?
- When were requirements for products/services verified?
- What type of nonconformities require acceptance under concession (by customers/authorities)?

Examples of process evidence:

- Verification and validation records
- Test plan/instruction/control plan
- Test records
- Checklist
- Special release form customer or government agency (if applicable)
- Product specifications
- List of persons authorized to grant release

8.7 Control of nonconforming outputs

Summary/interpretation:

Handling of nonconforming products or services

Additional notes:



- The organization must maintain documented information on nonconformities, the actions initiated and acceptance under concession where appropriate, as well as the function responsible for deciding on the relevant actions.
- The requirements for documented information have been clearly expanded in the new standard. For example, the organization now also needs to name the authority responsible for deciding on the actions (correction, segregation, acceptance under concession etc.) to address the nonconforming outputs.

Examples of audit questions:

- How does the organization handle nonconforming products/services?
- How does the organization internally analyze nonconforming products/services and which improvements have resulted therefrom?
- Which categories/classes has the organization defined for the various types of nonconformities with requirements, and how does it address them?
- How does the organization consider rework in test plans?

Examples of process evidence:

- Evidence of control of nonconformities
- Segregated storage area for blocked parts, labeling
- Fault report, nonconformities
- Special release by customer
- Coordination with the customer
- Procedure/Process description control of nonconforming outputs/products
- Rework plan
- Labeling instructions

9 Performance evaluation

This clause addresses the requirements for

- performance evaluation including the necessary measurements (9.1),
- internal audits (9.2), and
- management review (9.3).

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Summary/interpretation:

Definition of what needs to be monitored and measured when, by whom, and why and how the results will be handled and documented.

Additional notes:



- The organization must retain appropriate documented information as evidence of the monitoring, measuring, analysis and evaluation results.
- To verify fulfillment of the objectives, the organization must – as a minimum requirement – monitor (frequently without measuring equipment) and measure (with equipment) the processes, design and development outputs (in as far as applicable), production/service provision and customer satisfaction. Appropriate and informative parameters/key performance indicators (KPIs) are necessary for this purpose.

- The results of the evaluation can be included as input into the management review.
- External service providers/laboratories, if any, might need to hold accreditation.
- The organization must demonstrate that the provided services are in conformity with the requirements and evaluate the effectiveness of the quality management system.

Examples of audit questions:

- How does the organization monitor, measure, analyze and evaluate QMS performance and effectiveness, including intervals and evaluation criteria?
- How does the organization ensure that only tested and calibrated monitoring and measuring equipment will be used?

Examples of process evidence:

- Criteria for performance evaluation and QMS effectiveness
- Results of monitoring and measuring performed
- Test flowchart/work plan
- Test plan/control plan
- Test certificates
- Quality control chart
- Quality records
- Sampling plans (attributive and variable samples)
- Reference samples
- Process indicators (KPIs)



9.1.2 Customer satisfaction

Summary/interpretation:

The organization must determine customer satisfaction and must define the methods for doing so.

Additional note:

- One key change is that the new standard requires the organization to monitor customers' perception of the degree to which their expectations have been met. In other words, the organization must systematically determine and analyze information on customers' (subjective) satisfaction or dissatisfaction.

Examples of audit questions:

- Which customers does the organization choose for monitoring information on customer satisfaction and why?
- What do customers think of the organization?
- What methods does the organization use to determine the customers' perception of the degree to which their needs and expectations are fulfilled?

Examples of process evidence:

- Customer satisfaction or customer opinion surveys
- Analysis of complaints and warranties
- Market-share analysis
- Benchmarking
- Analysis of customer inquiries
- Evaluation of customer surveys



9.1.3 Analysis and evaluation

Summary/interpretation:

The organization must analyze and evaluate information from customer-satisfaction surveys.

Additional notes:

- Every organization defines what data must be analyzed and evaluated, how frequently this has to be done and what improvement actions result therefrom.
- The results of data analysis and evaluation are intended to provide useful inputs for strategic decisions and management review.
- Data analysis and evaluation can be performed more often than, for example, management review. They can be performed in monthly status meetings, or also in situations such as daily shop-floor meetings.
- Examples of possible data for analyzing QMS effectiveness could include:
 - Process capability (cpk)
 - Number of nonconformities
 - Scrap and rework rates
 - On-time delivery
 - Evaluation of customer satisfaction
 - Target/performance comparison (project management)

Examples of audit questions:

- What actions have resulted from the evaluations of monitoring, measuring and customer satisfaction?
- How frequently does the organization analyze and evaluate data and information?
- Why does the organization analyze and evaluate data (for which processes, areas, activities do the analysis results serve as inputs)?

Examples of process evidence:

- Root cause analysis
- Complaints analysis
- Evaluation of customer complaints
- Warranty analysis
- Analysis of the results of product, process and system audits
- Analysis of the performance of external providers
- Action list
- Target/performance comparison report

9.2 Internal audit

Summary/interpretation:

Internal processes must be checked at regular intervals so that suitable corrections and corrective actions can be determined and implemented.



Additional notes:

- The organization must maintain documented information as evidence of the implementation of the audit program and the audit results.
- The standard explicitly requires an internal report of audit results to top management.
- Change management must now be considered in the audit program.
- The organization must establish, implement and maintain an audit program for internal audits based on the requirements of ISO 9001:2015. The audit program must increasingly consider changes that affect the organization.
- The organization must review the internal audit program for risk-based thinking (e.g. frequency, sites, processes, binding obligations), regular updating and the expertise of internal auditors.
- The entire QMS must be internally audited within the scope of a 3-year cycle. However, not all processes need to be audited annually.
- The organization must provide justifications for any exceptions from the annual internal audits at individual sites in multi-site organizations. All sites must be subjected to an internal audit within a 3-year cycle.
- Internal auditors must not audit their own activities.

Examples of audit questions:

- Which criteria has the organization considered in its definition of the audit program (e.g. how stable, critical, or complex are the individual processes; which changes have been implemented in the QMS; results of other audits, nonconformities, complaints etc.)?
- Which effectively implemented actions have resulted from internal audits?
- Which requirements have been defined for internal auditors?
- Have the internal auditors received training on the content of the new standard?

Examples of process evidence:

- Documented information as evidence of internal audit reports and action lists
- Internal audit program (frequency)
- Nonconformity report
- Auditor qualification
- Auditor appointment
- Audit planning
- Procedure/process description: Internal audits

9.3 Management review

9.3.1 General

Summary/interpretation:

Top management must review the quality management system at regular intervals to ensure its continuing suitability, adequacy and effectiveness, and its alignment with the strategic direction of the organization.

Additional notes:

- A full management review must be carried out annually.
- Objective of the management review is to check the suitability, adequacy, effectiveness and strategic direction of the organization.

Examples of audit questions:

- On what aspects is management review based (e.g. internal criteria, centralized, decentralized)?
- How often does the organization perform management review?

Examples of process evidence:

- Date of the last management review
- Action list



9.3.2 Management review inputs

Summary/interpretation:

The organization must determine which information it needs for the management review.

Additional notes:

- The organization must define sufficient inputs for the management review and these inputs also need to be available (e.g. results of internal audits, KPIs, supplier evaluations, opportunities for improvement etc.)

Examples of audit questions:

- Which inputs for management review has the organization defined?
- Which areas provide information as inputs for management reviews?
- Which necessary data was surveyed and evaluated?

Examples of process evidence:

- Previous management review
- Internal/external objectives (organization-/product-/customer-related) from the previous year
- Trend analysis
- Process indicators
- Customer-satisfaction analysis
- Quality objectives
- Process analysis (KPIs)
- Action list
- Monitoring and measurements
- Reports of internal audits/process audits/product audits
- Analysis of external providers
- Benchmarking
- Feedback from relevant interested parties

9.3.3 Management review outputs

Summary/interpretation:

The organization must document the outputs of the management review. The outputs must include information on opportunities for improvement/necessary resources.



Additional notes:

- The organization must retain documented information of the outputs of the management review.
- The organization must use its own findings to check the outputs of the management review for plausibility/appropriateness (e.g. surveys of participants, in particular top management, review of inputs).
- Management review should include information on how to improve QMS performance and effectiveness based on defined criteria.

Examples of audit questions:

- To what extent does the organization maintain documented information as evidence of the management review results (e.g. separate complete report, agenda items of several meetings, lists of participants, presentations, records)?
- Which actions have resulted from the management review to improve the QMS?
- Which weaknesses of the QMS has the organization identified in the management review?

Examples of process evidence:

- Management review
- Results of the management review
- Business plan
- Strategy plan
- Project plan
- Action list

10 Improvement

The organization shall make use of opportunities for improvement to meet customer requirements and enhance customer satisfaction. The organization should take into account the results of the analysis and evaluation of QMS performance, internal audits and management review when taking actions for improvement.

10.1 General

Summary/interpretation:

Top management of the organization must commit to continual improvement of the QMS and to the improvement of products and services, in order to meet requirements and take into account future needs and expectations.

Additional notes:

- The organization should take into account the results of the analysis and evaluation of QMS performance, internal audits and management review when taking corrective actions.
- Continual improvement shall be demonstrated with the help of suitable indicators as evidence.
- The objective of any improvement is to fulfill

customer requirements, needs and expectations today and in the future.

- Examples of improvement include corrective actions, continual improvement, changes, innovation and reorganization.

Examples of audit questions:

- What opportunities for improvement has the organization identified?
- How has the organization established and implemented the necessary actions resulting therefrom?
- How have QMS performance and effectiveness noticeably improved based on defined criteria?

Examples of process evidence:

- Process improvement
- Improvement of products and services
- Improvement of the quality management system
- Action list
- Design and development projects



10.2 Nonconformities and corrective actions

Summary/interpretation:

The organization must determine the handling and root-cause of nonconformities and the corrective actions resulting therefrom.

Additional notes:

- The organization must maintain documented information as evidence of the type of nonconformity, the actions taken and the results of corrective actions.
- The standard does not require any procedures or processes for handling actual and potential nonconformities or for taking corrective and preventive actions.
- This clause shows that a QMS is primarily a tool of prevention.
- The concept of preventive actions is included throughout the standard, including clause 6.1 "Actions to address risks and opportunities."
- The objective is to ensure that nonconformities will not recur at a different time or place. Where recurrence cannot be excluded completely, it should at least be reduced.
- What is important is that the actions taken and their consequences are monitored. Further actions could be necessary.
- For nonconformities and the actions resulting therefrom, the following must be included: binding obligations, process indicators, quality objectives, process control requirements, results of internal audits, risks and opportunities and others.
- Steps must be taken to ensure that corrective actions aim at the actual cause of the nonconformity (quality of root cause analysis).
- Updating the risks and opportunities determined during planning may even be necessary.

Examples of audit questions:

- How does the organization check the effectiveness of corrective actions?
- Which sources of nonconformities does the organization consider?
- How did the organization determine the causes of nonconformities (examine examples)?
- How does the organization ensure that nonconformities will not recur at another time or place?

Examples of process evidence:

- Change project
- Documented information of nonconformities and results of corrective actions
- Quality management plan
- Corrective actions list
- Suggestion system
- Complaint analysis
- 8D report
- Procedure/process description: Nonconformities and corrective actions
- Complaints
- Failure analysis
- Design and development projects

10.3 Continual improvement

Summary/interpretation:

The QMS of an organization must be continually improved and enabled to identify needs (risks) or opportunities that must be addressed in the future.

The results of analysis and evaluations and the outputs of management review serve as a starting point for continual improvement.

Additional notes:

- Continual improvement must be proved as a minimum requirement within the 3-year surveillance period.
- If there is no documented information as evidence of continual improvement of the QMS (e.g. in the case of organizations that are already at the level of the best available technology) alternative methods/projects (e.g. Six Sigma, Lean, 5S, Kaizen, Scrum, Kanban, benchmarking) must be addressed.

Examples of audit questions:

- How does the organization evaluate whether continual improvement actions need to be considered?
- Which methods does the organization apply to continually improve?

Examples of process evidence:

- CIP (Continual improvement process)
- Suggestion system
- Management review
- Quality management plan
- Improvement proposal system of the QMS
- Key performance indicators of the QMS



Annex 1 – Overview of the documentation requirements of EN ISO 9001:2015



standard element		Documentation requirements
4.3	Scope	Scope Types of products and services Justification of non-applicable requirements
4.4	Processes	Documented information that supports the operation of processes Documented information as evidence that processes are carried out as planned
5.2.2	Quality policy	Documented information on quality policy
6.2	Quality objectives	Documented information on quality objectives
7.1.5.1	Monitoring and measuring resources	Documented information as evidence of the resources' fitness of purpose for monitoring and measurement
7.1.5.2	Measurement traceability	If no standard exists, the basis of calibration or verification must be available
7.2	Competence	Appropriate documented information as evidence of the competence of individuals
7.5.1	Documented information – General	Documented information required by the standard Documented information which the organization deems necessary for QMS effectiveness
7.5.3	Control of documented information	Information about the control of documented information
8.1	Operational planning and control	Documented information must be determined, maintained, and retained to the extent necessary to give confidence that the processes have been carried out as planned, and to demonstrate that the conformity of products and services has been ensured.
8.2.3	Review of the requirements for products and services	Documented information of the review results and of all new requirements for products and services must be retained (if applicable)
8.2.4	Changes to requirements for products and services	Amendment of documented information if requirements for products and services change
8.3.2	Design and development planning	The organization must maintain the required documented information to confirm design and development requirements
8.3.3	Design and development inputs	Documented information on design and development inputs
8.3.4	Design and development controls	Documented information of the activities to control the design and development process
8.3.5	Design and development outputs	Documented information on design and development outputs
8.3.6	Design and development changes	Documented information on design and development changes, results of reviews, authorization of changes, and actions initiated to prevent adverse impacts
8.4.1	Control of externally provided processes, products, and services	Documented information on the following activities: results of evaluation, selection, monitoring of performance, re-evaluation of external providers, and all necessary actions

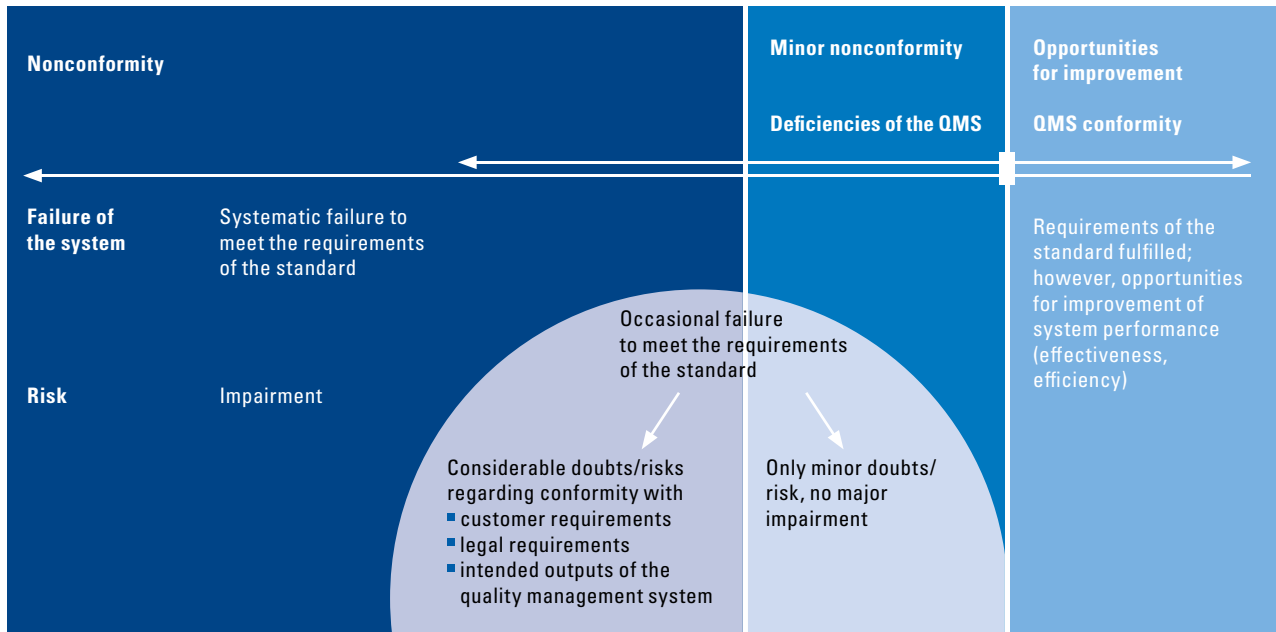
Annex 1 – Overview of the documentation requirements of EN ISO 9001:2015

standard element	Documentation requirements
8.5.1 Control of production and service provision	Documented information on the characteristics of the products to be produced/services to be provided and the outcomes to be achieved
8.5.2 Identification and traceability	Documented information that enables traceability
8.5.3 Property belonging to customers or external providers	Documented information if property of customers or external providers is lost, damaged etc.
8.5.6 Control of changes	Documented information of the results of the review of changes, including the names of the person(s) authorizing said changes and any necessary activities arising from the review
8.6 Release of products and services	Documented information about the release of products and services, including evidence of conformity with the acceptance criteria and traceability to the persons authorizing the release
8.7 Control of nonconforming outputs	Documented information on nonconformities, the actions initiated, and acceptance under concession, where appropriate, as well as the function responsible for deciding on the relevant actions
9.1.1 Monitoring, measurement, analysis, and evaluation	Appropriate documented information as evidence of the monitoring, measuring, analysis, and evaluation results
9.2 Internal audit	Documented information as evidence of the implementation of the audit program and the audit results
9.3.3 Management review outputs	Documented information as evidence of the results of management reviews
10.2 Nonconformities and corrective action	The organization must maintain documented information as evidence of the type of nonconformity, the actions taken, and the results of corrective actions

Annex 2 – Mandatory elements to be audited in each audit (certification, re-certification and surveillance audit):

- 5.1.1 Leadership and commitment
- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 7.5 Documented information
- 8.1 Operational planning and control
- 9.1.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review
- 10.2 Nonconformity and corrective actions
- 10.3 Continual improvement

Annex 3 – Evaluation of audit findings





We look forward to hearing from you

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Explanation:



Documented information
must be available