# ISO 9001:2015 Transition – Evidence Guide

Purpose:

This document provides a guide about interpretation and acceptable evidence that demonstrates compliance to the new requirements of ISO 9001:2015 Standard. It also provide examples of questions and examples of walk around evidence to help Assessors determine whether an organisation is meeting the requirements of the criterion. The questions are intended as supplement only, and do not try to cover all aspects. This document will assist clients and Assessors to better understand the requirements, and accordingly assist clients to better plan their transition process.

The document does not define new structure, new numbering scheme and removed requirements as changes; rather the document only indicates new and amended requirements.

The examples of documents and/or records give guidance about some of the paperwork that would assist in meeting the requirements of the criterion. It must be noted however, that the examples are not suggested as the only or preferred ways of meeting the criterion, nor should they be interpreted as a list which all organisations must have. An organisation may have different ways of meeting the requirements of the criterion and the examples should not detect from this.

It is expected that there are many questions that would be asked in addition to the questions listed in this document.

Symbols Key
ⓘ Explanation of a subclause
☐ Examples of documents / records
↻ Observations of operational activities
❓ Discussions or questions that may assist

New requirements of ISO 9001:2015 Standard and examples of acceptable evidence
NOTE: A complete list of ISO 9001:2015 requirements has been provided as a checklist including the identification of the new requirements.

4.1 Understanding the organisation and its context

Does the organisation determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system?

Does the organisation monitor and review information about these external and internal issues?

> ⓘ **What is it?** To understand the context of the organisation is a process; it is not a one-off exercise. This process determines factors which influence the organisation's purpose, objectives and sustainability. It considers internal factors such as values, culture, knowledge and performance of the organisation. It also considers external factors such as legal, technological, competitive, market, cultural, social and economic environments.
>
> Examples of the ways in which an organisation's purpose can be expressed include its vision, mission, policies and objectives. These should be framed against its scope of activities and core services / products.

The way in which organisations manage risks varies depending on their business context (e.g. potential consequences of product / service failure).

Part of understanding the context of the organisation is to identify its interested parties. The relevant interested parties are those that provide significant risk to organisation sustainability if their needs and expectations are not met.

To understand which issues can be important, an organization should consider those that:
- Are key drivers and trends
- Can present problems
- Reflect changing circumstances
- Can be leveraged for beneficial effect, including improved quality performance
- Present opportunities for competitive advantage, including cost reduction, value for customer

The organisation's environment should be regularly monitored to determine if there is a need to review and (when appropriate) revise the strategy and policies. The organisation should have processes to:

- Continually monitor and regularly analyse the organisation's environment, indulging its customers' needs and expectations, the competitive situation, new technologies, political changes, economic forecasts, or sociological factors
- Assess its current processes and capabilities and resources
- Identify future resource and technology needs
- Update its strategy and policies; and

Rational behind it: To enable organisations to adapt to their varying influencing business drivers.

Changes in circumstances / changes in business environment may prevent organisations from consistently providing products and services that meet customer requirements. This requirement is intended to prevent the quality of services or products to deteriorate over time due to changes in business environment. It will assist organisations to <u>consistently</u> provide products and services that meet customer requirements, which is one of the main purposes of a QMS.

We live in a dynamic world where organisations must transform if they are to deliver sustained value to their shareholders and stakeholders. All too easily in this highly connected world, hard-earned competitive advantages and reputation can slip away. One such competitive advantage is the sustained delivery of standout quality products and services.

Definitions

Context of the organisation: combination of internal and external issues that can have an effect on an organisation's approach to developing and achieving its objectives.

Note 1: The organisation's objectives can be related to its products and services, investments and behaviour towards its interested parties.

Note 2: The concept of context of the organisation is quality applicable to not-for-profit or public service organisations as it is to those seeking profits.

Note 3: In English, this concept is often referred to by other terms such as "business environment", "organisational environment" or "ecosystem of an organisation".

	Note 4: Understanding the infrastructure can help to define the context of the organisation. **Strategy:** a locally structured plan or method for achieving objectives, especially over a long period.

📄	• A SWOT (Strengths, Weaknesses, Opportunities and Threats) Analysis Report
	• A PEST (Political, Economic, Social and Technological) Analysis Report
	• A Strategic Business Plan
	• A document that lists the issues
	• A Business Continuity Plan
	• A procedure that describes how the issues are identified on an ongoing basis
	• Evidence of workshop / meeting, e.g.
	   ○ Calendar invitations
	   ○ Minutes
	   ○ Emails
	• List of attendees

❓	• How do you manage the current issue of …….? • What are the current external issues that might prevent you from achieving the established your environmental performance objectives? • Asking the CEO / CFO / CSO / CIO about a change / expected change in the industry that could impact on the business and how they are planning to address it?

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, does the organisation determine:

a) the interested parties that are relevant to the quality management system?
b) the requirements of these interested parties that are relevant to the quality management system?

Does the organisation monitor and review information about these interested parties and their relevant requirements?

ⓘ	Part of the process of understanding the context of the organisation is to identify its interested parties. The relevant interested parties are those that provide significant risk to organisation sustainability if their needs and expectations are not met. Organisations define what results are necessary to deliver to those relevant interested parties to reduce that risk. Organisations attract, capture and retain the support of the relevant interested parties they depend upon for their success. The Standard is applicable where an organisation needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction. There is no requirement for the organisation to consider interested parties where it has decided that those parties are not relevant to its QMS. It is for the organisation to decide if a particular requirement of a relevant interested party is relevant to its QMS. **Interested party:** stakeholder; person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity. EXAMPLE Customers, owners, people in an organisation, providers, banders, regulators, unions, partners or society that can include competitors or opposing pressure groups.

📄	• Stakeholders engagement records such as:
	    ○ Meeting minutes
	    ○ Emails
	    ○ Relevant stakeholders list that identifies the communication methods and contact detail
	    ○ Stakeholders engagement reports
	    ○ Meeting calendar invitations
	• A procedure that describes the ongoing engagement method

❓	• Who are your relevant stakeholders / interested parties? • How do you manage the requirements of ……. (a stakeholder)? • What are the requirements of …… (a stakeholder) • What is the frequency of engaging with your stakeholders?

4.4 Quality management system and its processes
4.4.1

Does the organisation:

f) address the risks and opportunities as determined in accordance with the requirements of 6.1?

📄	• Risks & Opportunities Register
	• Evidence of risk assessment, e.g.
	    ○ Meeting minutes for meeting conducted between environmental representatives and department managers
	    ○ Emails
	    ○ Calendar invitations

5 LEADERSHIP
5.1 Leadership Commitment
5.1.1 General

Does top management demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system?
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organisation?
c) ensuring the integration of the quality management system requirements into the organisation's business processes?
d) promoting the use of the process approach and risk-based thinking?
g) ensuring that the quality management system achieves its intended results?
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system?
i) promoting improvement?
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?


📄	• Evidence that the changes have been considered, e.g.
	    ○ Evidence of meeting of environmental representative with HR, e.g.
	        ▪ Meeting minutes
	        ▪ Calendar invitations
	        ▪ Emails
	• Evidence of amending senior management job descriptions, e.g.
	    ○ Draft versions of Job Descriptions
	    ○ Draft version of employment contracts

	• Evidence of training, e.g.
	    ○ External training certificate regarding personal obligations of senior managers such as senior executives, board members to ensure the business remains compliant to ISO 14001:2015
	    ○ Induction training records
	    ○ Meeting minutes
	    ○ Calendar invitations
	    ○ Emails
	• A clear link between the (or total integration) between the organisation's business plan and its environmental objectives
	• Evidence that environmental criteria are embedded into product design
	• Evidence that top management request performance results and undertake feedback, review and future goal setting, e.g.
	    ○ Emails

?	• Asking the CEO / CIO / CFO / CSO about the new responsibilities that have been assigned to them as a result of the new change? • Asking the CEO / CIO / CFO / CSO etc. about the new activities that they are undertaking as a result of the assignment of new responsibilities • How many members of the top management team are involved? • What is the percentage of leaders and senior managers who have completed environmental management training? • What's the number of levels of management with specific environmental responsibilities?

5.1.2 Customer focus

Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that:

b)the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed?

What is it? Leadership is demonstrated through decisions and statements made by senior staff. When making decisions and statements, senior staff should allocate resources to ensure that risks and opportunities related to QMS performance are assessed, and consider those risks and opportunities when making decisions. **Rational behind it:** Sustained success is achieved when an organisation attracts and retains the confidence of customers and other interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to the sustained success of the organisation. ⓘ Definitions Customer: person or organisation that could or does receive a product or a service that is intended for or required by this person or organisation. EXMPLE Consumer, client, end-user, retailer, receiver of product or service from an internal process, beneficiary or purchaser Note 1: A customer can be internal or external to the organisation. **Examples** 1. A repeated pattern of bard decisions to cut operating budget despite the reviewed analysis regarding the potential deteriorating of quality of service / products, highlights a non-fulfilment of this requirement.

	2. The recent case when Thomas Dudley Woods has been jailed after intentionally fudged fumigation certificates of chickpeas exported to India highlights a non-fulfilment with this requirement. 3. A repeated pattern of decisions made by a Managing Director of certified engineering firm to make number of senior positions redundant despite warnings from an independent consultant regarding the negative impact that those decisions will have on the quality of service provided.

📄	• Evidence that the changes have been considered, e.g.
	   ○ Evidence of meeting of environmental representative with HR, e.g.
	     ▪ Meeting minutes
	     ▪ Calendar invitations
	     ▪ Emails
	• Evidence of training, e.g.
	   ○ External training certificate regarding personal obligations of senior managers such as senior executives, board members to ensure the business remains compliant to ISO 14001:2015
	   ○ Induction training records
	   ○ Meeting minutes
	   ○ Calendar invitations
	   ○ Emails
	• News reports

❓	• Interview with senior staff, e.g. CEO, CIO, CFO, MD, GM regarding the methodology of addressing risks and opportunities.

5.2 Policy
5.2.1 Establishing the quality policy

Does top management establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organisation and supports its strategic direction?

📄	• An electronic copy of the policy on the organisation's webpage
	• Policy contained in the organisation's annual report
	• Policy included in induction material
	• Policy included in tender documentation
	• Evidence of review of environmental policy, e.g.
	   ○ Draft versions of policy
	   ○ Emails
	   ○ Meeting minutes
	• Calendar invitations

↻	• Policy on display in reception / visitor areas

5.2.2 Communicating the quality policy

Is the quality policy:

c) available to relevant interested parties, as appropriate?

📄	• Annual report
	• Newsletters
	• Stakeholder engagement records that include the quality policy, e.g.
	   ○ Meeting minutes
	   ○ Emails

5.3 Organisational roles, responsibilities and authorities
N/A

6.1 Actions to address risks and opportunities
6.1.1

When planning for the quality management system, does the organisation consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s)?
- b) enhance desirable effects?
- c) prevent, or reduce, undesired effects?
- d) achieve improvement?

Does the organisation plan:

- a) actions to address these risks and opportunities?
- b) how to:
  1) integrate and implement the actions into its quality management system processes (see 4.4)?
  2) evaluate the effectiveness of these actions?

Are actions taken to address risks and opportunities proportionate to the potential impact on the conformity of products and services?

What is it?

The organisation is required to identify risks and opportunities related to QMS performance and take appropriate actions to address them.

Risk is inherent in all aspects of a QMS. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are identified, considered and controlled throughout the design and use of the QMS.

Not all the processes of a QMS represent the same level of risk in terms of the organisation's ability to consistently provide services and products that meet their customer requirements. Some need more careful and formal planning and controls than others. Under the requirements of 6.1, the organisation is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

ⓘ Although 6.1 specifies that the organisation shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organisations can decide whether or not to develop a more extensive risk management methodology than is required by ISO 9001:2015, e.g. through the application of other guidance of standards.

Rational behind it: By considering risk throughout the system and all processes the likelihood of achieving stated objectives is improved, output is more consistent and customers can be confident that they will receive the expected product or service. Risk-based thinking:
- improves governance
- establishes a proactive culture of improvement
- assists with statutory and regulatory compliance
- assures consistently of quality of products and service
- improves customer confidence and satisfaction
- enables the organisation to focus on those matters of significance within the QMS.

Examples:

1. The highest risks of <u>architects and project management engineers</u> are due to exposures stemming from errors, omissions and negligence in the preparation of plans, designs, drawings and specifications. Other exposures include failure to comply with legal requirements, such as environmental regulations. Hence, such organisations should focus its efforts on mitigating these risks by establishing enough controls on recruiting and on-going evaluation of experienced professionals.

2. The highest risks of Building Construction General Contractors (i.e. risks of not delivering projects on-time or delivering projects with quality problems) are mainly related to the difficulty of managing extensive number of workers that some building projects may require, and following specifications and building codes. Hence, General Contractors should focus their efforts on managing their subcontractors, and hiring practices for managers and other supervisors.

3. The highest risk of demolition contractors is the possibility of damaging nearby structures that could occur long after work has been finished on a site. Hence, demolition contractors should focus their efforts on determining condition of nearby structures before any demolition work begins though activities such as pre-demolition inspection of adjacent facilities, complete with corresponding photographs or video footage.

Definitions

Risk: effect of uncertainty

Note 1: An effect is a deviation from the expected positive or negative.

Note 2: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3: Risk is often characterised by reference to potential events and consequences, or a combination of these.

Note 4: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.
Note 5: The word "risk" is sometimes used when there is the possibility of only negative consequences.

Examples

Scenarios

- Risks & Opportunities Register
- Evidence of risk assessment, e.g.
  - Meeting minutes for meeting conducted between environmental representatives and department managers
  - Emails
  - Calendar invitations
- Employee Induction

- How do you manage the risk of ….. ?
- What are the most significant 3 risks that you have identified?
- What's the number of employees that have environmental requirements into their job descriptions
- What's the number of employees participating in environmental programmes (e.g. suggestion, recycle, clean-up initiatives)?

6.2 Quality objectives and planning to achieve them
6.2.1

Are quality objectives:
e) monitored?

	What is it? Monitoring of quality objectives is carried out through the use of performance indicators and/or supervision, checking or critically observing. An organisation should establish measurable performance indicators. Such indicators should be objective, verifiable and reproducible. They should be appropriate to the organisation's activities, products and services, consistent with the quality policy, practical, cost-effective and technologically feasible. The organisation should consider the use of both management and operational indicators. QMS planning is not a singular event, rather it is an ongoing process. Plans evolve as the organisation learns and circumstances change. The KPIs should be suitably cascaded as performance indicators at relevant functions and levels within the organisation to support the achievement of top level objectives. **Rational behind it:** To track an organisation's progress in achieving its objectives. **Definitions** **Objective:** result to be achieved. Note 1: An objective can be strategic, tactical, or operational. Note 2: Objectives can relate to different disciplines (such as financial, health and safety, and environmental objectives) and apply at different levels (such as strategic, organisation-wide, project, product and process). Note 3: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective or by the use of other words with similar meaning (e.g. aim, goal or target). Note 4: In the context of QMS quality objectives are set by the organisation, consistent with the quality policy to achieve specific results. **Quality objective:** objective related to quality. Note 1: Quality objectives are generally based on the organisation's quality policy Note 2: Quality objectives are generally specified for relevant functions, levels and processes in the organisation. **Indicators:** Measurable representation of the condition or status of operations, management or condition. **Monitoring:** determining the status of a system, a process or an activity Note 1: to determine the status, there might be a need to check, supervise or critically observe.
	• A document lists all indicators and data management method
?	• What is the number of achieved objectives and targets? • What's the number of organisational units achieving objectives and targets?

6.3 Planning of changes

Does the organisation consider:

a) the purpose of the changes and their potential consequences?

b) the integrity of the quality management system?
c) the availability of resources?
d) the allocation or reallocation of responsibilities and authorities?

|	• Change management plan • Change risk assessment

7 SUPPORT
7.1 Resources
7.1.1 General

Does the organisation consider:

b) what needs to be obtained from external providers?

	The organization should identify the internal and external resources that are needed for the achievement of the organization's objectives in the short and long term. The organization's policies and methods for resource management should be consistent with its strategy. To ensure that resources (such as equipment, facilities, materials, energy, knowledge, finance and people) are used effectively and efficiently, it is necessary to have processes in place to provide, allocate, monitor, evaluate, optimize, maintain and protect those resources. To ensure the availability of the resources for future activities, the organization should identify and assess the risks of potential scarcity, and continually monitor current use of resources to find opportunities for improvement of their use. In parallel, research for new resources, optimized processes and new technologies should take place.

	• QMS planning records (business plan drafting records), e.g.
	   o Meeting minutes
	   o Meeting calendar
	   o Process map draft revisions

7.1.2 People
N/A

7.1.3 Infrastructure
N/A

7.1.4 Environment for the operation of the processes
N/A

7.1.6 Organisational knowledge

Does the organisation determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services?

Is this knowledge maintained and made available to the extent necessary?

When addressing changing needs and trends, does the organisation consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates?

	What is it? Top management should assess how the organisation's current knowledge base is identified and protected. Top management should also consider how to obtain the knowledge required to meet the present and future needs of the organisation from internal and external

sources, such as academic and professional institutions. There are many issues to consider when defining how to identify, maintain and protect knowledge, such as
- Learning from failures, near miss situations and successes,
- Capturing the knowledge and experience of people in the organisation,
- Gathering knowledge from customers, suppliers and partners,
- Capturing undocumented knowledge (tacit and explicit) that exists within the organisation,
- Ensuring the effective communication of important information content (particularly at each interface in the supply and production chains), and
- Managing data and records.

ISO 9001:2015 addresses the need to determine and manage the knowledge maintained by the organisation, to ensure the operation of its processes and that it can achieve conformity of products and services.

Knowledge management is the planning, organising, motivating and controlling people, processes and systems in the organisation to ensure that its knowledge-related assets are improved and effectively employed. Knowledge-related assets include knowledge in the form of documents such as patents and manuals, knowledge stored in electronic repositories such as a "best-practices" database, employee's knowledge about the best way to do their jobs, knowledge that is held by teams who have been working on focused problems and knowledge that is embedded in the organisation's products, processes and relationships.

The process of knowledge management include acquisition, creation, refinement, storage, transfer, sharing and utilisation. The knowledge management function in the organisation operates these processes, develops methodologies and systems to support them, and motivates people to participate in them.

Knowledge management is an organisational activity that focuses on what managers can do to enable knowledge management's goals to be achieve, how they can motivate individuals to participate in achieving them and how they can create social processes that will facilitate knowledge success. Social processes include expert networks – networks that are established to allow those with less expertise to contact those with greater expertise. Organisation's computer-based communications and information systems such as "lessons learned" repositories, and directories and networks, such as those designed to put organisational participants in contact with recognised experts in a variety of topic areas represent other form of knowledge protection processes.

Examples of knowledge management strategies:
1. Create knowledge "maps" or directories and networks to connect people
2. Providing groupware and intranets to facilitate communities of practice
3. Socialisation as a means of knowledge creation and exchange; emphasizes the providing of physical "places" to facilitate discussions
4. Creating and refining knowledge repositories and on motivating people to provide content
5. Developing and using repeatable processes that are supported with knowledge from previously conducted processes
6. The management of intellectual property such as patent, trademarks

Examples of knowledge management issues
1.

Rational behind it: Requirements regarding organisational knowledge were introduced for the purpose of

a) safeguarding the organisation from loss of knowledge, e.g.
- through staff turnover;
- failure to capture and share information;

	b) encouraging the organisation to acquire new knowledge as its business context changes, e.g. - learning from experience; - mentoring; - benchmarking

📄	• A record of on online forum discussion
	• Evidence of organisation expert networks, e.g.
	    o Emails
	    o Calendar invitations
	    o Pictures

❓	• How do you ensure that unwritten knowledge are transferred from experience staff to new staff?

7.2 Competence
N/A

7.3 Awareness
Does the organisation ensure that persons doing work under the organisation's control are aware of:

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance?

d) the implications of not conforming with the quality management system requirements?

📄	• Induction records • Induction power point presentation
❓	• Can workers / representatives confirm that they receive information about quality policy and objectives

7.4 Communication

Does the organisation determine the internal and external communications relevant to the quality management system? Including:

    a) on what it will communicate?
    b) when to communicate?
    c) with whom to communicate?
    d) how to communicate?
    e) who communicates?

📄	• A procedure that describes the ongoing stakeholder engagement method? • Documented consultation procedure • Minutes of team briefings

7.5 Documented information
7.5.1 General
N/A

7.5.2 Creating and updating
N/A

7.5.3 Control of documented information
N/A

8 OPERATION

8.1 Operational planning and control

Does the organisation plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

b)establishing criteria for:

2) the acceptance of products and services?

📄	• Inspection and Test Plans / Key Task Plans • Procedure / work instructions

8.2 Requirements for products and services
8.2.1 Customer communication

Does communication with customers include:

d) handling or controlling customer property?

📄	• Request for Quote
	• Records of meeting with customers, e.g.
	   o Minutes
	• Emails from customer
	• Application review records, e.g.
	   o Meeting minutes
	   o Emails
	• Procedure describing the above requirements
	• Induction material
	• Induction records

8.2.2 Determining the requirements for products and services
N/A

8.2.3 Review of the requirements for products and services

Does the organisation conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post delivery activities?

📄	• Request for Quote
	• Application review records, e.g.
	   o Meeting minutes
	   o Emails

8.2.4 Changes to requirements for products and services
N/A

8.3 Design and development of products and services
8.3.1 General

8.3.2 Design and develo9pment planning

In determining the stages and controls for design and development, does the organisation consider:

a)the nature, duration and complexity of the design and development activities?
e)the internal and external resource needs for the design and development of products and services?
i) the level of control expected for the design and development process by customers and other relevant interested parties?
j) the documented information needed to demonstrate that design and development requirements have been met?

📄	• Design / development programmes with checkpoints appropriate to the extent of each phase and the stages of which evaluations of the product and process will take place. • Design programme development meetings, e.g. ○ Minutes ○ Email ○ Calendar invitations

8.3.3 Design and development inputs

Does the organisation determine the requirements essential for the specific types of products and services to be designed and developed? Does the organisation consider:

e) potential consequences of failure due to the nature of the products and services?

📄	• Design risk assessment and analysis records

8.3.4 Design and development controls
N/A

8.3.5 Design and development outputs
N/A

8.3.6 Design and development changes
N/A

8.4 Control of externally provided processes, products and services
### 8.4.1 General
N/A

8.4.2 Type and extent of control

Does the organisation:

    c) take into consideration:

        1) the potential impact of the externally provided processes, products and services on the organisation's ability to consistently meet customer and applicable statutory and regulatory requirements?

What is it? In selecting and evaluating suppliers and partners, the organisation should consider the risks associated in the relationships with the suppliers and partners. ⓘ **Definitions** **External provider:** external supplier; provider that is not part of the organisation.

	EXAMPLE: Producer, distributor, retailor or vendor of a product or a service. **Provider:** supplier; organisation that provides a product or a service Note 1: A provider can be internal or external to the organisation. Note 2: In a contractual situation, a provider is sometimes called "contractor"
📄	• Evidence of risk assessment, e.g. o Risk assessment register
❓	• What is the risk level of your XYZ Pty Ltd supplier? • What are the controls associated with different risk levels?

8.4.3 Information for external providers
N/A

8.5 Production and service provision
8.5.1 Control of production and service provision

Controlled conditions shall include, as applicable?

a) the availability of documented information that defines:

    2) the results to be achieved?

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met?

📄	• Product inspection reports • Project sign-off records
❓	• Has the organisation determined the criteria for acceptability for demonstrating the suitability of equipment? • Is suitable monitoring and measurement equipment available when and where necessary to ensure conformity of the product or service?

8.5.6 Control of changes

Does the organisation review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements?

Does the organisation retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review?

ⓘ	**What is it?** To achieve the benefits associated with changes, the organisation should consider all types of changes that may need to occur. These changes may be generated, for example, in:
	    • processes
	    • documented information
	    • tooling
	    • equipment
	    • employee training
	    • supplier selection
	    • supplier management
	    • and many others

There are many triggers that can cause a change to the QMS:
- Customer feedback
- Customer complaint
- Product failure
- Employee feedback
- Innovation
- Determined risk
- Determined opportunity
- Internal audit results
- Management review results
- Identified nonconformity
- Many others

In order to sort through the required changes, the organisation should consider a method to prioritise. To determine the priority, the organisation should consider a methodology that allows them to take into account:
- Consequences of the change
- Likelihood of the consequences
- Impact on customers
- Impact on interested parties
- Impact on quality objectives
- Effectiveness of process that are part of the QMS
- Others

Typically steps to implement changes are:
- Define the specifics of what is to be changed
- Have a plan (tasks, timeline, responsibilities, authorities, budget, resources, needed, information, others)
- Engage other people as appropriate in the change process
- Develop a communication plan (appropriate people within the organisation, customers, suppliers, interested parties, etc. may need to be informed)
- Use a cross functional team review the plan to provide feedback related to the plan and associated risks
- Train people
- Measure the effectiveness

What changes may need to be made?
- Change to a process (inputs, activities, outputs, controls)
- Communication with customers
- Communication with the supply chain
- Additional controls of processes
- Inspection
- Employee training
- Implement a new process
- Provide documented information
- Change existing documented information
- Improve employee competence
- Outsource a process

Other considerations
- Prior to making a change, the organisation should consider unintended consequences
- After making a change the organisation should monitor the change to determine its effectiveness and to identify any additional problems that might be created.
- Records of some changes may be needed as part of the QMS.

	Rational behind it: This requirement addresses changes at operational level. This is to ensure that the organisation is adaptive to influences at operational level.
	Definitions
	Change control: <configuration management> activities for control of the output after formal approval of its product configuration information.
	Product configuration information: requirement or other information for product design, realisation, verification, operation and support.
	Configuration: interrelated functional and physical characteristics of a product or service defined in product configuration information
	Configuration baseline: approved product configuration formation that establishes the characteristics of a product or service at a point in time that services as reference for activities throughout the life cycle of the product or service.
📄	- Evidence that the changes have been considered, e.g. - Evidence of meeting of environmental representative with HR, e.g. - Meeting minutes - Calendar invitations - Emails

9.3 Management review
9.3.1 General

Does top management review the organisation's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organisation?

📄	- Quality management review program - Schedule of reviews - Records of reviews - Business continuity plan
❓	- When the quality management system scheduled for review? - How does top management ensure that the QMS align with the strategic direction and context of the organisation?

10 IMPROVEMENT
10.1 General

Does the organisation determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction?

Do these include:

a) improving products and services to meet requirements as well as to address future needs and expectations?
b) correcting, preventing or reducing undesired effects?

①	Improvement, innovation and learning can be applied to: - products - processes and their interfaces - organisational structure - management systems - human aspects and culture - infrastructure, work environment and technology, and

	- relations with relevant interested parties Fundamentals to effective and efficient improvement, innovation and learning is the ability for the enablement of the people in the organisation to make informed judgements on the basis of data analysis and the incorporation of lessons learned. Improvement activities can range from small-step continual improvements at a work place to significant improvement of the entire organisation. The organisation should define objectives for the improvement of its products, processes, organisational structures, and its management system through the analysis of data. The organisation should ensure that continual improvement becomes established as a part of the organisational culture by: - providing the opportunities for people in the organisation to participate in improvement activities, through their empowerment - providing the necessary
📄	• Annual company report and financial accounts. • Forecasts/backcasts/scenario planning/strategy planning • Strategic report • Capital allocation report
↻	• Inspection of new facilities, equipment • Interview of new recruited skilled employees
❓	• What's the % of training budget allocated to quality management? • What's the number of quality improvement projects implemented?

10.2 Nonconformity and corrective action

When a nonconformity occurs, including any arising from complaints, does the organisation:

b)evaluate the need for action to eliminate the cause(s) of the nonconformity?, in order that it does not recur or occur elsewhere, by:

3) determining if similar nonconformities exist, or could potentially occur?

e)update risks and opportunities determined during planning, if necessary?

f) make changes to the quality management system, if necessary?

📄	• Corrective action register • Corrective action report

10.3 Continual improvement

Does the organisation consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement?

ⓘ	**Rational behind it:** Successful organisations have an ongoing focus on improvement. Improvement is essential for an organisation to maintain current levels of performance, to react of changes in its internal and external conditions and to create new opportunities. Some key benefits include: - Improved process performance, organisational capability and customer satisfaction - Enhance focus on root cause investigation and determination, followed by prevention and corrective actions

- Enhanced ability to anticipate and react to internal and external risks and opportunities - Enhanced consideration of both incremental and breakthrough improvement - Improved use of learning for improvement - Enhanced drive for innovation **Definitions** **Continual improvement:** recurring activity to enhance performance. Note 1: The process of establishing objectives and finding opportunities for improvement is continual process through the use of audit findings and audit conclusions, analysis of data, management, reviews or other means and generally leads to corrective action or preventive action.

📄	• Annual company report and financial accounts. • Forecasts/backcasts/scenario planning/strategy planning • Strategic report • Capital allocation report

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