# The importance of context in ISO 9001

ISO 9001 Quality Management Systems

# How context sets the scene for your quality management system

**Understanding the context of an organization is a fundamental element of Annex SL – the high level structure that is common to all new and revised ISO standards, including ISO 9001.**

**For an organization to succeed, there must be a clear understanding of where they are and where they want to go. That is why defining organizational context is so important in the quality management system (QMS) standard, ISO 9001.**

In terms of ISO 9001, 'context' is a thorough determination and understanding of the internal and external issues that can impact an organization and its objectives. It can be done for all organizations irrespective of size, industry or geographical location.

Context is crucial to designing and implementing effective management systems with a focus on delivering planned organizational performance, including satisfying customers' needs and meeting the expectations of stakeholders or interested parties.

In many ways, context is one of the most important components of ISO 9001. Earlier versions of the standard implied that the organization should consider the context. Now, context is a key requirement of ISO 9001 and should be effectively addressed by all organizations.

Context helps to link the objectives of the QMS to the overall strategic objectives of the organization. Clause 4 focuses on linking the outputs from 'Context of the Organization' with the strategic direction and other core business processes as defined in Clause 5 – Leadership.

For a management system to be effective it must be aligned with the overall strategy and purpose of the organization. By doing so, management systems can be a powerful tool to direct, enable, measure and guide the performance of an organization.

The 'Context of the Organization' clause in ISO 9001 has been designed to help organizations really understand their needs and the needs of its stakeholders' or interested parties'.

There are four areas for organizations to consider:

## Understanding the organization and its context.

This is an overall assessment, defined by top management and company strategists, that establishes the objectives and purpose of the organization. They must determine the past, current and potential future internal and external issues to be addressed to meet the organizational goals.

## Understanding the needs of interested parties.

This is a complete assessment of stakeholders, both internal and external, and what it will take to meet their expectations and be compliant with all requirements.

## Determining the scope of the management system.

This is the crucial step that defines how the management system will be designed and built to help address internal and external issues that are considered priorities and/or necessities by top management.

## Defining the management system and its processes.

This sets out what processes are needed for the management system, including tasks, management controls and checkpoints. It also considers levels of performance evaluation, data collection and analysis to enable organisations to gauge the effectiveness of the management system.

This helps manage emerging risks and opportunities, while also driving improvement in response to known failures.

## Why is context important?

Frequently changing internal and external circumstances affect many organizations. Given that every organization has a unique set of issues, no two organizations should have identical management systems.

An output of the context review and evaluation may be documented and used to identify and address these internal and external issues, that collectively represent the key challenges facing organizations. Without a complete and accurate assessment of context, a management system runs a very high risk of being ineffective or misplaced.

To gain certification to ISO 9001, organizations – irrespective of their size, industry or geographical location – must properly scope and design a management system that addresses the opportunities, issues and risks specific to their strategic objectives and purpose. Simply put, without a proper understanding of the context, there can be no certification of a management system.

While the task may appear daunting, it can have the beneficial effect of empowering management. Organizations can use their management system to suit their unique circumstances, strategy and goals, while also satisfying the needs of customers, stakeholders and other interested parties.

Doing so allows management systems to be more effective and more closely integrated to the essential functions of the business, adapting to changing business environments and stakeholder requirements.

## What is covered by the context of the organization?

ISO 9001 differentiates between internal and external issues. Internal issues focus on topics within the company, such as strategy, structure and the management system itself. When it comes to internal issues, the organization has greater decision-making authority and ability to plan. Internal issues carry their own set of opportunities and risks that help shape the organizational context.

External issues are those that exist outside the organization, which have an effect on its operations but are largely beyond its direct influence and control.

A common framework for evaluating external issues is the PESTLE model. This represents the conditions politically, economically, socially, technologically, legally and environmentally that influence, shape and regulate the organization. While it is not necessary to use such a model, it helps deliver a complete picture and provides a framework to compare when re-determining context in the future.

Incorporating significant internal and external issues into the scope and design of the management system allows it to address risks, opportunities or known failures that relate to strategy, structure, system and the needs of interested parties.

Determining the context of an organization works together with the leadership and risk elements of ISO 9001.

Top management is often the best positioned group to define context by documenting the important internal and external issues that directly relate to the strategic objectives.

Meeting the requirements for context allows an organization's management system to be properly determined in terms of scope, purpose and the design, build and execution of processes required for the management system to be effective.

## How does context drive cultural engagement and improve organizational effectiveness?

A common criticism of previous versions of the standard was the lack of connection between quality issues and the everyday business operations. They were often viewed as separate and not in the remit of many employees. A thorough determination of organizational context helps solve this.

By identifying internal and external issues, known as risks, opportunities or known failures (i.e., nonconformities), they can be used to determine the scope and design of the management system.

With these issues directly relating to the strategic direction and purpose of the business, the management systems then become a useful part of daily business and a relevant platform for employees to track performance.

When designing a management system based on context, risks and opportunities are then prioritized by top management, not the quality manager.

This means a broad spectrum of departments and functions have a role to play in contributing to the management system.

This paints a clearer picture of how each employee contributes to the objectives of the company, driving a higher level of cultural engagement. The Plan-Do-Check-Act (PDCA) approach to all management systems then provides a path for iterative improvement available across the entire organization.

## What business benefits are gained through defining organizational context?

Perhaps the most important and beneficial aspect of ISO 9001, is the requirement to align the QMS with the overall business strategies and practices.

Stakeholder analysis is crucial to this as it drives the scope, purpose and objectives of the management system. Without it, it is nearly impossible to create an effective and compliant system.

The QMS is no longer dictated by the standard, internal auditors or the quality manager. Instead, it is the top management that is empowered, providing them with the authority and flexibility to define their management system. Through the alignment of the QMS to strategy and purpose, it allows the organization to systematically manage the most important risks and opportunities, with no reduction in quality objectives.

With the path to success for many organizations hinging on their ability to innovate or adapt to change, the outputs of context keep a business and its management system current and effective.

## Ensure your organization effectively considers its context.

Every organization has a unique set of internal and external issues and you need to make sure your organization has the systems and processes in place to evaluate, analyze and respond to its ever-changing environment.

Working with an impartial partner that has years of expertise to provide insight, clarity and understanding of the requirements of the standard can make certification to ISO 9001 less complicated and more effective.

LRQA recognizes that every organization and its QMS are unique. At LRQA, we take time to understand the needs and unique circumstances of our clients and their businesses, to act with judgement, sensitivity and care. Our independence means that we are committed to doing things the right way to reach the highest standards and best outcomes for all, giving our clients confidence in our decisions every time.

## How we can help

Certification to ISO 9001 presents organizations with a great opportunity to enhance leadership within their business through a unique and powerful management system. To do this, it is beneficial to have an independent partner who can thoroughly and impartially assess individual business needs, with the expertise and skills to create solutions.

### Training

We provide practical ISO 9001 training courses, led by trained and qualified tutors. Many of our courses are endorsed by relevant professional bodies and based on our experience of assessing management systems.

We offer both public and in-house training services including tailored training solutions through our customized assurance services.

### Gap analysis

This assessor-delivered activity enables you to focus on critical, high risk or weak areas of your system prior to your formal assessment visit. Whether you are in the early stages of implementing your collaborative relationship management system or are looking for a 'dry run', the scope can be decided by you.

### Assessment and certification

We specialize in management systems compliance, all underpinned with expert advice designed to meet the needs of your industry. We explore every problem thoroughly with exact, analytical precision. We leave no stone unturned and no questions unanswered, to draw accurate conclusions.

### Impartiality

We maintain our impartiality by proactively managing conflicts of interest across all LRQA businesses including those which may exist between consultancy and third-party certification services.

## Why choose LRQA?

We're here to help negotiate a rapidly changing world, by working with you to manage and mitigate the risks you face. From compliance to data-driven supply chain transformation, it's our job to help you shape the future, rather than letting it shape you. We do this by delivering:

### Strategic vision

Our technical know-how, sector expertise and innovative, forward-thinking approach will help you meet the challenges of today – and become a safer, more secure, and sustainable organization tomorrow.

### Technical expertise

Our people are sector experts. They bring with them a clear understanding of your specific challenges, standards and requirements – then deploy deep knowledge of certification, brand assurance, food safety, cybersecurity, inspection and training to help you meet them.

### Global capability

Operating in more than 120 countries, recognized by over 30 accreditation bodies worldwide, and covering almost every sector, we can help you manage risk, drive improvement and build credibility with stakeholders around the globe.

### Effective partnership

Every business is unique. That's why our experts work with you, to fully understand your needs and goals, and work out how we can best support them.

### Fresh perspective

We have led the way in shaping our industry and continue to take every opportunity to collaborate with clients and pioneer new ideas, services and innovation.

**LRQA**

**YOUR FUTURE. OUR FOCUS.**

## About LRQA:

By bringing together unrivaled expertise in certification, brand assurance, food safety, cybersecurity, inspection and training, we've become a leading global assurance provider.

We're proud of our heritage, but it's who we are today that really matters, because that's what shapes how we partner with our clients tomorrow. By combining strong values, decades of experience in risk management and mitigation and a keen focus on the future, we're here to support our clients as they build safer, more secure, more sustainable businesses.

From independent auditing, certification and training; to technical advisory services; to real-time assurance technology; to data-driven supply chain transformation, our innovative end-to-end solutions help our clients negotiate a rapidly changing risk landscape – making sure they're shaping their own future, rather than letting it shape them.

### Get in touch

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