G0001-03

Clause-by-Clause Guide

User Guide — Manufacturing Business Edition

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4. Context of your Organization

4.1 Understanding Organizational Context

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

Use the F0410-01_Context_Analysis_Register to document any external and internal issues relevant to your organization's operational purpose and strategic direction that may affect its ability to achieve the intended result of the management system.

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

Examples of organizational issues might include:

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

You will need to identify and understand the various quality conditions and internal and external issues typically encountered in your type of organization, which can have both positive and negative impacts. Ensure that your organization has considered the relevance of climate change and, if found relevant, has included it in your organization’s objectives (6.2) and when evaluating risks and opportunities (6.1).

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

Use the F0410-01_Context_Analysis_Register.xlsx to collate evidence to provide assurance that your organization is regularly, or as necessary, reviewing and updating its external and internal issues. Although there is no requirement for documented information to define the context of the organization, your organization will find it helpful to retain the types of documented information listed below to help demonstrate compliance:

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

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Reviewing your organization's context could include interviews with senior management, questionnaires, surveys, and research. Cross-functional input is essential to the specific expertise required to identify the full breadth of issues, including finance, training, human resources, commercial, engineering, and design.

This will ensure a broader appreciation of the context and a more comprehensive engagement, particularly with functions not previously involved in the quality management system.

Identifying Internal Issues

SWOT Analysis Template is a tool that can help you analyse what your company does best now and devise a successful strategy for the future. SWOT can also uncover areas of the business that are holding you back or that your competitors could exploit if you don't protect yourself.

A SWOT analysis examines internal and external factors, that is, what is happening inside and outside your organization. So, some of these factors will be within your control, and some will not. In either case, the wisest action you can take in response will become clearer once you've discovered, recorded, and analysed as many factors as possible.

Strengths are characteristics of our organization that enable us to operate more efficiently and effectively than competitors. What do you do well? What unique resources can you draw on? What do others see as your strengths? Consider:

1. What does our organization do well?
2. What advantages does our business have over other internal sections or external organizations, including competitors?
3. What makes our organization different from competitors?

Strengths are what your organization does exceptionally well or in a way that distinguishes it from its competitors. Think about the advantages your organization has over others.

These might include your operators' and engineers' skill and experience, the depth of your process and product knowledge, the consistency of your delivery performance, the maturity of your tooling and production equipment, your accumulated process capability data on key products, or the strength of long-standing customer and supplier relationships.

Weaknesses are areas that are recognized as needing improvement. What could you improve? Where do you have fewer resources than others? What are others likely to see as weaknesses? Consider:

1. What can be done better?
2. What causes problems or complaints (information from root cause analysis)?
3. Which capabilities need to be modified, strengthened, or divested for the future?

Weaknesses, like strengths, are inherent features of your organization, so focus on your people, resources, systems, and procedures. Think about what you could improve and the sorts of practices you should avoid.

Opportunities are trends, circumstances, or business opportunities that can be leveraged. What opportunities are open to you? What trends could you take advantage of? How can you turn your strengths into opportunities? Consider:

1. What are the changes in technology or markets?
2. What local and global events may be helpful?
3. What are the changes in customer/societal values?

Opportunities are openings or chances that arise from situations outside your organization, requiring an eye on what might happen in the future. They might arise as developments in the market you serve or the technology you use. Spotting and exploiting opportunities can make a massive difference to your organization's ability to compete and take the lead in your market.

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Threats can be external or internal, which can adversely affect business or operations. External threats could include economic factors, new legislation, or a new competitor in the market. Internal threats could include skill or staff shortages within our organization. What threats could harm you? What is your competition doing? What threats do your weaknesses expose you to? Consider:

1. What obstacles are there for ongoing operation?
2. Are there any potential competitors to the business?
3. Who might be the new competition?
4. Are there any potential changes to staffing, products, processes, or technology that could threaten the operation or business?

Threats include anything that can negatively affect your business from the outside, such as supply chain issues, shifts in market requirements, or a shortage of recruits. It is vital to anticipate threats and take action against them before you become a victim or your growth stalls.

Consider the obstacles you face in winning and retaining customers. Product expectations move quickly — customers now compare your product quality, lead time, and total cost of ownership against the best available globally, not just against other suppliers in your sector.

Customer specifications, regulatory and statutory requirements, and material restrictions (RoHS, REACH, conflict minerals, food contact, biocompatibility) evolve, and your product design and manufacturing processes must keep pace.

Emerging technology (Industry 4.0 connectivity, automation, machine-vision inspection, predictive maintenance, additive manufacturing, advanced materials) is an ever-present threat to legacy production models and an opportunity for those who adopt early.

Identifying External Issues

A PESTLE analysis is a management framework and diagnostic tool suitable for analysing and understanding external factors. The outcome of the analysis will help you to understand factors external to your organization.

A workshop approach often allows ideas to be shared and provides an effective, efficient way to achieve a valuable outcome. The workshop could be a discussion identifying the issues that can be mapped using the Political, Economic, Social, Technological, Legal, and Environmental (PESTLE) framework to examine how these factors influence the organization.

Use our PESTLE Analysis Template and the examples below to explore the external influences affecting your organization. This method helps structure the conversation and helps achieve buy-in for what is often seen as a peripheral or niche area.

Determine how government policy and legislation impact your business. What is happening **politically** in the environment in which you operate?

1. Trading policies;
2. Funding, grants, and initiatives;
3. Home market lobbying/pressure groups;
4. International pressure groups;
5. Wars and conflict;
6. Government policies, terms, and change;
7. Inter-country relationships and attitudes;
8. Political trends;
9. Internal political issues;
10. Shareholder needs and demands.

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How do corporate social responsibility and environmental issues affect the company? What is happening concerning ecological and **environmental** issues?

1. General market conditions that affect the business;
2. Market direction;
3. Environmental issues;
4. Relevance of climate change;
5. Environmental regulations;
6. Stakeholder/investor values;
7. Needs for the organization's products and services in the market;
8. Customer market technology opportunities;
9. Competitors and differences between competitors;
10. Competitiveness of the organization and what affects its ability to compete;
11. Customer problems and complaints with current products and services.

How are new technologies, automation, and the pace of technological change impacting your business? What is happening **technology-wise** that can impact what you do?

1. Maturation of existing technologies;
2. Technological developments or trends that affect or could affect the business;
3. New product development and potential markets: government, international, OEM, automotive, aerospace, medical, etc.;
4. Productivity improvements through automation;
5. Telecommunication infrastructure;
6. Online connectivity and digital data.

What trends and lifestyle changes might impact your business? What is occurring **socially and culturally** in the markets in which you operate?

1. Current or emerging trends in lifestyle and their implications;
2. Demographic trends that may affect market size (growth rate, income, population shifts);
3. Whether these trends represent an opportunity or a threat;
4. Changes in consumer behaviour;
5. Increasing environmental awareness;
6. Urbanization;
7. Consumer demands, personalization, and high-end experiences;
8. Public demand for transparency and participation in decision-making.

Could any pending legislation or taxation changes affect your business positively or negatively? What is happening with changes to **legislation**?

1. Possible changes in regulation/legislation;
2. Impacts of these changes on business;
3. Stability of government;
4. Outsourcing regulations;
5. Government bureaucracy – rules and regulations;
6. Legal constraints.

What economic factors like growth, inflation, and interest rates affect your business? What is happening within the **economy**?

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1. National and internal financial trends (trends in economic forces);
2. Economic trends that may have an impact on business activity;
3. Emerging markets;
4. Inflation, employment levels, supply;
5. Energy available;
6. Global financial situation.

There is no requirement for the outputs of Clause 4.1 to be documented. If you currently discuss and consider the issues verbally during management review meetings, continue to do so. If your organization already retains documentation of strategic planning results via PESTLE analysis forms or Management Review Minutes, then climate change considerations should be captured in those documents.

4.2 Needs & Expectations of Interested Parties

Interested Parties are stakeholders who receive your products, may impact your organization, or otherwise have a significant interest in it. Similar to the context review discussed above, cross-functional input is vital, as certain functions will identify with particular stakeholders, such as procurement with suppliers and sales with customers.

A workshop approach should be encouraged, which can be undertaken independently or in conjunction with the context review workshop. Ensure that your organization has properly identified its interested parties and subsequently determined whether any of their needs and expectations should be adopted. Ensure this process is revisited periodically, as relevant interested parties' requirements may change over time.

ISO 9001:2026 adds a third determination to Clause 4.2: having identified the relevant interested parties and their relevant requirements, the organization must determine which of these requirements will be addressed through the quality management system. Auditors will expect the Interested Parties Register to show, for each adopted requirement, where in the QMS it is addressed, and the register notes that interested parties can have climate-related requirements.

Although not explicitly required, objective evidence could be a list or matrix of the interested parties, their corresponding needs and expectations, and an indication of which of these might be accepted:

1. All relevant legal requirements;
2. Consideration of whether interested parties (4.2) have requirements that relate to climate change;
3. All requirements imposed by upper levels in the organization (for example, corporate requirements);
4. All relevant requirements of relevant interested parties that the organization decides to comply with, whether contractually (customers) or voluntarily (environmental or safety commitments).

To determine the relevance of an interested party or its requirements, your organization needs to answer: ‘Does this interested party, or their requirements, affect the organization’s ability to achieve the intended outcomes of its quality management system?’ If yes, the interested parties’ requirements should be captured. There are many ways to capture this information, and your approach might include:

1. Information summarized as part of inputs to risk and opportunity registers;
2. Recorded in a simple spreadsheet;
3. Logged and maintained in a database;
4. Captured and recorded through key meetings.

The needs and expectations of interested parties can initially be captured in the F0420-01_Interested _Parties_Register.xlsx file.

Using this template, the respective Departmental Managers should identify and list the needs and expectations of any interested parties, including those related to climate change in their department, that may have a potential impact on the achievement of your organization’s quality objectives and policy and the conformity of your management system.

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Also, use the worksheets to map out and understand the expectations of relevant interested parties, and how you plan to address their requirements through the management system. This information should be retained as a strategy or tactical planning document to underpin your organization's policies and to provide a roadmap for achieving future goals.

Based on the scoring output, consider and implement the handling approaches outlined in the tables below to meet and address the needs and expectations of our interested parties. Rank the interested parties by their degree of Priority and Relevance (1 low, 5 very high) to current objectives, policies, and the conformity of the products and services offered. The spreadsheet multiplies these scores to generate an overall Power score that represents the Risk Priority Number (RPN), which prioritizes the adoption of relevant needs or expectations.

1. **Relevance** – effects upon organizational activities;
2. **Priority** – effects on the decisions the organization makes;
3. **Power** – combined effects of influence the interested party has (Risk Priority Number RPN).

Interested Party Scoring Matrix

Power (Effects of influence) = Priority x Relevance		**Relevance** of Interested Party (Effects on activities)				
		Very Low	Minor	Medium	High	Very High
Priority of Interested Party (Effects on decisions)	Very Low	1	2	3	4	5
	Minor	2	4	6	8	10
	Medium	3	6	9	12	15
	High	4	8	12	16	20
	Very High	5	10	15	20	25

Action Matrix

Score	**Power** of Interested Party (Effects on decisions)		
	Description	Strategy	Objectives
Very Low	No relevance, low priority	Monitor interest	None
Minor	Low relevance, medium priority	Engage to expand interest	Detect opportunities from growing interest
Medium	Medium relevance, high priority	Keep satisfied	Build interest, monitor for changes
High	High relevance, high priority	Keep informed	Maintain interest, monitor for changes
Very High	Very high relevance, high priority	Manage closely	Maintain support, monitor for changes

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Very High	Very high relevance, high priority	Manage closely	Maintain support, monitor for changes

Communicating with stakeholders, particularly, is vital. Communication with stakeholders should be based on performance data generated by your organization's quality management system, which will require robust monitoring and measurement to ensure that the data is reliable.

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You should ensure that the monitoring and measurement processes are included in the internal audit programme so your organization can assure itself that the verification processes are validated and that the data it communicates is accurate.

There is no requirement for the outputs of Clause 4.2 to be documented. If you currently discuss and consider the requirements verbally during management review meetings, continue to do so. If your organization already maintains documentation of the requirements of interested parties, climate change considerations should be captured in those documents.

The Interested_Parties_Register.xlsx file should be reviewed by Top management for acceptance and incorporation into the management system, either by adding it to the scope or by incorporating it into customer requirements, operational activities, process controls, and risk and opportunity registers.

4.3 Quality Management System Scope

You will need to verify that your organization's scope exists as documented information (which may be in the form of a Manual) in accordance with Clause 7.5.1a. Verify that the organization's scope has been established, considering its boundaries and the applicability of the quality management system.

Evaluate the process by which the scope was determined and review any process or procedure, if present. The lack of documented processes will require more reliance on objective evidence from interviews.

Look for confirmation that your organization has determined the boundaries and applicability of the quality management system to establish its scope concerning any external and internal issues referred to in 4.1 and the requirements of relevant interested parties referred to in 4.2.

The scope of your quality management system may include the whole organization, specific and identified functions within the organization, specific sections of the organization, or one or more functions across a group of organizations.

1. Has your organization determined the boundaries and applicability of the quality management system to establish its scope?
2. Has your organization effectively considered the following before determining the scope of the quality management system?
3. Has your organization effectively considered the extent of its control and influence, context, external and internal issues, physical and functional boundaries, activities, products, and services?
4. Has your organization made its scope available to all interested parties as documented information? A statement from your organization that the scope can be provided upon request may be accepted as objective evidence.

Check that this is done, taking into account your organization's context and the products and services it offers. You should review any exclusions from the standard for ongoing suitability and relevance. Check that legacy issues with limited scope and omitted activities do not affect conformity. Check that they are recorded and that the rationale for the exclusion is stated and justified.

4.4 Quality Management System Processes

ISO 9001 includes specific requirements necessary for adopting processes when developing, implementing, and improving a management system. This requires your organization to systematically define and manage processes and their interactions to achieve the intended results in accordance with both the quality policy and strategic direction. Auditors will want to determine:

1. How well is the 'process approach' understood in the organization?
2. Is the management system in line with the organization's context and the requirements of interested parties?
3. Is it likely that the established quality management system will achieve its intended outcomes and enhance quality performance?

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