



Integrated Clause-by- clause Guidance

ISO 9001:2015, ISO 14001:2015 &
ISO 45001:2018



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4 About Your Organization

4.1 Organizational Context

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

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

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

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

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

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

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

2. Recorded in a simple spreadsheet;
3. Logged and maintained in a database;
4. Captured and recorded through key meetings.

The needs and expectation of interested parties can initially be captured using the Context & Interested Parties Matrix. Using this template, the respective Departmental Managers should identify and list the needs and expectations of any interested parties in relation with their department that may have potential impact on the achievement of your organization’s objectives and policy, the conformity of our products, services and management system.

Figure 1: Capturing Context & Interested Party Requirements

The screenshot shows a spreadsheet with the following structure:

- Row 1:** Title "Context & Interested Parties" and a descriptive text box.
- Row 2:** A legend table for "Priority of Interested Party (Effects on activities)".
- Row 3:** Column headers: 4.1 External Issues, 4.1 Internal Issues, 4.2a Interested Party, 4.2b Interested Party Requirements, 4.2c Criteria & Methods, 4.3 QMS Scope Applicability, 4.3 QMS Scope Exclusion(s).
- Row 4:** Sub-headers for 4.2a: Priority (1 to 4), Relevance (1 to 4), Power (P x R).
- Row 5:** Data row 1: Customer perception (External), Impact on future business (Internal), Current customer (Party), Priority 4, Relevance 4, Power 16. Requirements: Requirements documented by the contract, Kept satisfied, Kept informed. Criteria: Monthly Business Ops Meeting, Manage closely, Increase repeat orders. Applicability: Customer process. Exclusion: None.
- Row 6:** Data row 2: Too few qualified suppliers (External), Impact on priority and quality of build (Internal), Suppliers (Party), Priority 3, Relevance 4, Power 12. Requirements: Defined procurement frequency and quantity, On-time payment. Criteria: Supplier performance evaluation report and auditing, Review cost of build based on required/requested material specs. Applicability: Yes. Exclusion: None.
- Row 7:** Data row 3: Outside competition for recruitment (External), Job performance (Internal), Employees (Party), Priority 3, Relevance 3, Power 9. Requirements: Good benefits package/fair pay, Safe and healthy environment, Keep informed, Working time arrangements. Criteria: Monthly Business Ops Meeting, Auditing, Appraisals. Applicability: Yes. Exclusion: None.

Also, use this table to map out and understand the expectations of relevant interested parties and how you plan to deal with 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 road map to achieve future goals.

Based on the scoring output, consider and implement handling approaches, defined in the tables below, to manage and comply with the needs and expectations of our interested parties.

The Context & Interested Parties Matrix should be reviewed by Top management for acceptance and incorporation into the management system via addition to the scope, or incorporation into customer requirements, operational activities, process controls, hazard and aspect registers, risk and opportunity registers, and legal and compliance registers.

The Context & Interested Parties Matrix ranks the interested parties according to their degree of Priority and their Relevance (1 low, 4 high) to current objectives, policies and conformity of products and services. The spreadsheet multiplies these scores to generate an overall Power score that represents the Risk Priority Number (RPN) that is used to prioritize the adoption of any relevant need or expectation.

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

Interested Party Scoring Matrix

Power (<i>Effects of influence</i>) = Priority x Relevance		Priority of Interested Party (<i>Effects on decisions</i>)			
		No importance	Minor importance	Some importance	Major importance
Relevance of Interested Party (<i>Effects on activities</i>)	Not relevant	1	2	3	4
	Minor relevance	2	4	6	8
	Influential	3	6	9	12
	Significantly relevant	4	8	12	16

Action Matrix

Score	Power of Interested Party (<i>Effects on decisions</i>)		
	Description	Strategy	Objectives
1 to 3	Low relevance with low importance	Monitor interest	Detect opportunities from growing interest
4 to 6	Low relevance with high importance	Keep satisfied	Build interest, monitor for changes
7 to 11	High relevance with low importance	Keep informed	Maintain interest, monitor for changes
12 to 16	High relevance with high importance	Manage closely	Maintain support, monitor for changes

Communicating with stakeholders, particularly in relation to legal and compliance obligations is vital. Communication with stakeholders should be based on performance data generated by your organization's EHQMS, which will require robust monitoring and measurement to ensure that the data is reliable. You should ensure that the monitoring and measurement processes are included in the internal audit programme so your organization can assure itself that the checking processes are validated and that the data it is communicating is accurate.

4.3 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 in consideration of organization's boundaries and applicability of the EHQMS.

There is now essentially a process by which a scope must be determined; simply declaring a scope and excluding product-related aspects without evaluating the new considerations is not acceptable. 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 EHQMS to establish its scope with reference to 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 EHQMS may include the whole of the 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 EHQMS to establish its scope?

2. Has your organization effectively considered the following prior to determining the scope of the EHQMS?
3. Has your organization effectively considered the extent of its control and influence, context, external and internal issues, compliance obligations, 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 has been done in consideration of your organization's context and your products. You should review any exclusions previously noted under ISO 9001:2008 for ongoing suitability. Check that legacy issues which limited scope and omitted activities do not affect product conformity. Check that they are recorded and that the rationale for the exclusion is stated and justified.

4.4 Management System Processes

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

1. How well is the 'process approach' understood in the organization?
2. Is the EHQMS in line with the organization's context, and requirements of interested parties?
3. Is it likely the established EHQMS will achieve its intended outcomes and enhance environmental, safety and quality performance?
4. Does it include the enhancement of EHQMS performance?
5. Does it include the desire to fulfil of legal and compliance obligations and objectives?

Existing operational procedures, work instructions and flow charts are valid examples of documented information and can be used to evidence the requirement for 'documented information to support the operation of processes is being met'. Check that process inputs and outputs are defined and review how each of the processes are sequenced and how they interact. Look for evidence that your organization has:

1. Assigned duties/process owners; (Clause 5.3)
2. Assessed risks and opportunities; (Clause 6.1)
3. Provided resources; (Clause 7.1)
4. Maintained and retained documented information. (Clause 7.5)
5. Implemented measurement criteria; (Clause 9.0)
6. Improved its processes and the EHQMS; (Clause 10.0)

Your organization should begin using quality, health & safety, and environmental performance indicators to control and monitor issues, and associated risks and opportunities. These types of objective evidence will indicate that your organization has successfully integrated the EHQMS processes into its business processes.

Evidence may include management reviewing EHQMS KPI's as part of regular business reviews, awareness of contractors and employees of EHQMS goals and expectations, etc. When auditing process performance and effectiveness; ensure that you prioritize the following:

1. Reviewing your organization's processes, their sequence and interactions, the identification of functions and assignment of responsibilities, and performance against requirements and defined measures, with focus on processes that directly impact the customer;
2. Reviewing the process for validation and approval of processes and process changes;
3. Reviewing the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel;
4. Reviewing the process-based management techniques, including the examination of process measures (e.g., quality, tact time, cycle time, output effectiveness, control limits, process capability determination);
5. Reviewing plans in place to ensure performance objectives/targets are monitored, measured, and analyzed in order to realize the planned activities and achieve the planned results (e.g., verify performance information, percentage of non-conforming parts/products, percentage OTD);
6. Promoting continual improvement by reviewing actions taken when objectives/targets are not met;
7. Pursuing audit trails addressing customer concerns or requests for corrective actions, performance against objectives, and relevant process controls.

4.4.1 Identifying Processes

Use the *Process Matrix* worksheet to align the clauses and requirements of ISO 9001:2015, ISO 14001:2015, and ISO 45001:2018 to the processes within your organization. The *Process Matrix* provides a very convenient overview of all the processes that make up your management system. Defining the sequence and interaction of processes is also a requirement. This process matrix itself can satisfy this requirement.

1. Enter the process/functional area names in Row 2, we've included examples to get you started. We've set the spreadsheet up with three primary process groups to denote their sequence.
2. Enter an 'X' in the cell if the process has responsibility for ensuring conformity to clause(s) listed below. Where one or more process shows an 'X' in the same row as the requirement, this indicates an interaction between processes.
3. Using the 'filter' drop-down menu, select 'X' to show the applicable clauses to each process.
4. After you're done populating this worksheet, copy columns 'F' to 'AC', and paste them in to the 'Process Matrix' worksheet in the *Internal Audit Programme* workbook.

Figure 2: Process Matrix Example

1 Process Responsibility Matrix		C	D	E	Management			Operation			Support			Other														
		ISO 9001:2015	ISO 14001:2015	ISO 45001:2018	Management System & Processes	Business Planning	Sales & Marketing	QEHS Management	Business Review & Improvement	Operational Planning	Order/Quote Fulfillment	Design & Development	Procurement & Supply	Production/Manufacturing	Inspection & Calibration (QC)	Storage, Packing & Shipping	Facilities & Maintenance	Corrective Action	Internal Audit	Customer Service	Human Resources & Training	Document Control & Knowledge	Other 1	Other 2	Other 3	Other 4	Other 5	Other 6
4	4.1 Context of the Organization	Q	E	HS	X	X																						
5	4.2 Relevant Interested Parties	Q	E	HS	X	X																						
6	4.3 Management System Scope	Q	E	HS	X	X																						