



Integrated Clause-by- clause Guidance

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



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3. Stability of government;
4. Outsourcing regulations;
5. Government bureaucracy – rules and regulations;
6. Legal constraints.

What is happening within the **economy**?

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

4.2 Relevant Interested Parties

Interested Parties are those stakeholders who receive your products or services, who may be impacted by them, or those parties who may otherwise have a significant interest in your organization. Similar to the context review discussed above, cross functional input is vital, as certain functions will identify with particular stakeholders, for example procurement with suppliers, and sales with customers.

A workshop approach should be encouraged which can be undertaken independent to, or in conjunction with the context review workshop. Once stakeholders and their requirements are identified, the next step is to consider which stakeholder requirements generate legal and compliance obligations.

Legal requirements should be identified before other requirements. You should also determine whether these groups' requirements are reviewed and updated as changes in their requirements occur, or when changes to your organization's EHQMS are planned.

Ensure that your organization has properly identified its interested parties, and subsequently determined if any of their needs and expectations to be adopted as a compliance obligation. Ensure that this process is revisited periodically because the relevant requirements of relevant interested parties may change over time.

Although not specifically required, objective evidence could be a list or matrix of the interested parties, their corresponding needs and expectations, and indication of which of these accepted as compliance obligations might include:

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

In order 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 EHQMS?' If the answer is yes, the interested parties' requirements should be captured. There are many ways to capture this information, and your approach might include:

1. Information summarised as part of inputs to risk and opportunity registers (e.g. for ISO 9001, ISO 14001 and ISO 45001 this could be an additional process in the identification of environmental aspects and impacts, and health and safety hazards and risks);

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".
- Row 2:** Definition of Interested Parties and instructions on how to use the template.
- Row 3:** A 3x3 grid for "Priority of Interested Party (Effects on activities)" with values: Not relevant (1, 2, 3), Minor relevance (2, 4, 6), Influential (3, 6, 9), Significantly relevant (4, 8, 12).
- Row 4:** Main table header with columns: Ref., External Issues, Internal Issues, Interested Party, 4.2a (Priority, Relevance, Power), 4.2b (Interested Party Requirements), 4.2c (Criteria & Methods), 4.3 (QMS Scope Applicability), 4.3 (QMS Scope Exclusion(s)).
- Row 5:** Data row 1: Ref. 1, External Issues: Customer perception, Internal Issues: Impact on future business, Interested Party: Current customer, Priority: 4, Relevance: 4, Power: 16, 4.2b: Requirements documented by the contract, 4.2c: Monthly Business Ops Meeting, 4.3: Customer process.
- Row 6:** Data row 2: Ref. 3, External Issues: Too few qualified suppliers, Internal Issues: Impact on priority and quality of build, Interested Party: Suppliers, Priority: 3, Relevance: 4, Power: 12, 4.2b: Defined procurement frequency and quantity, 4.2c: Supplier performance evaluation report and auditing, 4.3: Yes.
- Row 7:** Data row 3: Ref. 2, External Issues: Outside competition for recruitment, Internal Issues: Job performance, Interested Party: Employees, Priority: 3, Relevance: 3, Power: 9, 4.2b: Good benefits package/fair pay, 4.2c: Monthly Business Ops Meeting, 4.3: Yes.

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 Context of the Organization																											
4.1	4.1 Organizational Context	Q	E	HS	X	X																						
4.2	4.2 Relevant Interested Parties	Q	E	HS	X	X																						
4.3	4.3 Management System Scope	Q	E	HS	X	X																						
4.4	4.4 Management System Processes	Q	E	HS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

1. **Management** processes form the backbone of the management system and the business itself;
2. **Operation** processes are steps that you go through to give the customer what they want, e.g. from order acceptance to design through to delivery;
3. **Support** processes do not contribute directly to what the customer wants but do help the key processes to achieve it. Support processes include often human resources, finance, document control, training and facilities maintenance, etc.

A good way to do this is to think about how workflows through your organization. Consider how the inputs and outputs to the key processes flow from one process to the next, what sub-processes might exist within it and how the support processes link in. For now, ignore the standard, in fact put it in a draw and forget it exists. Instead focus on your key processes and how the departments interface with each other.

Certification auditors will expect to see a process model that explains the key processes of the business and how each relates and links to the others. The depth of process explanation may be as detailed as the company chooses but should be based on its customer and applicable regulations or statutory requirements, the nature of its activities and its overall corporate strategy.

4.4.2 Sequence & Interaction

The auditor must see evidence that the organization has determined their processes and that the interactions are also defined, all within the EHQMS manual. Subsequently, this includes the actual and technical inputs and outputs of the processes to show their inter-relationship.

Use the *Process Application* worksheet to assign requirements to relevant functions, processes, departments and teams to show how your organization establishes, implements, maintains and continually improves its management system, its processes and their interactions, in accordance with the requirements of ISO 9001:2015 Clause 4.4.1, ISO 14001:2015, Clause 4.4 and ISO 45001:2018 Clause 4.4.

Figure 3: Process Application Example

Process Name	4.4.1a Inputs	4.4.1a Activities	4.4.1a Outputs	4.4.1b Interaction	4.4.1c Criteria & Methods	4.4.1d Resources	4.4.1e Responsibility	4.4.1f Risks	4.4.1f Opportunities	4.4.1g Evaluation
Management System & Processes	Standards Management system data	Conformance to requirements	Customer satisfaction Compliance data/evidence	See IMS manual and interactions Map (Appendix 1) and Process Matrix	Process performance Process control	Defined in business plan	Top Management IMS Manager	Refer to the Risk & Opportunity Register	Refer to the Risk & Opportunity Register	Internal audit Business review met Scorecards/dashbo
Business Planning	interested party requirements Environmental risks OHS hazards Market research Customer feedback Organizational vision Past experience	Strategic planning Risk management	Business plan Key measures Communication Policies Objectives	See IMS manual and interactions Map (Appendix 1) and Process Matrix	Achievement of business plan Improvement of key measures Net income	Defined in business plan	Top Management	Refer to the Risk & Opportunity Register	Refer to the Risk & Opportunity Register	Internal audit Business review met Scorecards/dashbo
Sales & Marketing	Market research Innovation Competitive data Industry benchmarking	Explore new product opportunities Set pricing Develop marketing Publish sales literature	Pricing Design inputs Marketing media	See IMS manual and interactions Map (Appendix 1) and Process Matrix	Revenue growth Net income	Defined in business plan	Sales & Marketing Manager	Refer to the Risk & Opportunity Register	Refer to the Risk & Opportunity Register	Internal audit Business review met Scorecards/dashbo Customer feedback
QEHMS Management										
Business Review & Improvement										
Operational Planning										
Order/Quote Fulfillment										
Design & Development										
Production/Manufacturing										
Procurement & Supply										
Inspection & Calibration (QC)										
Stratone, Parkinn & Shannon										

The completed *Process Matrix & Application* workbook forms the basis for programming internal audits as well as becoming a roadmap to the entire management system that allows internal and external personnel to clearly understand how our organization's processes fit together by: