ISO 9001:2015 & ISO 45001:2018

ISO 9001:2015 & ISO 45001:2018

Contents

1	Intro	oduction	4
2	lmp	lementation & Development	5
	2.1	Managing the Change	5
	2.2	Top Management Commitment	6
	2.3	Implementation Team	6
	2.4	Management Review Meetings	7
		Choosing your Registrar	
3		Analysis	
4	_	out Your Organization	
		Organizational Context	
	4.1.1		
	4.1.2		
	4.2	Relevant Interested Parties	13
	4.3	Management System Scope	15
	4.4	Management System Processes	16
	4.4.1	I Identifying Processes	17
	4.4.2	2 Sequence & Interaction	18
	4.4.3	3 Outsourced Processes	19
5	Lead	dership & Governance	21
	5.1 Leadership & Commitment		21
	5.1.1	1 General	21
	5.1.2	2 Customer Focus	22
	5.2	Corporate Policy	23
	5.2.1	1 Establishing the Policy	23
	5.2.2		
	5.3	Roles, Responsibilities & Authorities	25
	5.4	Consultation & Participation of Workers	25
6	Plan	nning	29
	6.1 General		29
	6.1.1		
	6.1.2	2 Hazard Identification	37
	6.1.3	B Legal Requirements	40
	6.1.4	4 Planning Action	40

ISO 9001:2015 & ISO 45001:2018

6.2	. OI	bjectives	40
6	5.2.1	Objectives	
6	5.2.2	Objectives & Planning to Achieve Them	43
6.3	PI	anning for Change	44
7 S	Suppo	ort	46
7.1		esources	
	7.1.1	General	
	7.1.2	People	
7	7.1.3	Infrastructure	
7	7.1.4	Environment for the Operation of Processes	
7	7.1.5	Monitoring & Measuring	
7	7.1.6	Organizational Knowledge	
7.2	Co	ompetence	49
7.3	A	wareness	50
7.4	Co	ommunication	51
7	7.4.1	General	
7	7.4.2	Internal Communication	
7	7.4.3	External Communication	
7.5	D	ocumented Information	54
7	7.5.1	General	
7	7.5.2	Creating & Updating	
7	7.5.3	Control of Documented Information	55
8 (Opera	tion	58
8.1	O	perational Planning & Control	58
8	3.1.1	Quality Control	58
8	3.1.2	Occupational Health & Safety	58
8.2	. Re	equirements for Products & Services	60
8	3.2.1	Customer Communication	60
8	3.2.2	Determination of Requirements for Products & Services	61
8	3.2.3	Review of the Requirements for Products & Services	61
8	3.2.4	Changes to Requirements for Products & Services	62
8.3	D	esign & Development of Products & Services	62
8	3.3.1	General	62
8	3.3.2	Planning	62
8	3.3.3	Inputs	63
8	3.3.4	Controls	63
8	3.3.5	Outputs	64
8	3.3.6	Changes	64

ISO 9001:2015 & ISO 45001:2018

8.4 S	Suppliers & Purchasing	65
8.4.1	General	
8.4.2	Type and Extent of Control	65
8.4.3	Information for External Providers	66
8.5 P	Production & Service Provision	66
8.5.1	Control of Production & Service Provision	
8.5.2	Identification & Traceability	67
8.5.3	Property Belonging to Customers or External Providers	67
8.5.4	Preservation	68
8.5.5	Post-delivery Activities	68
8.5.6	Control of Changes	68
8.6 F	Release of Products & Services	69
8.7 N	Nonconforming Outputs	69
8.7.1	Product and Process Nonconformities	69
8.7.2	Service-based Nonconformities	71
8.8 E	mergency Situations	71
8.8.1	Identification of Potential Emergencies	72
8.8.2	Emergency Response Plans	72
8.8.3	Emergency Response Review	73
9 Perfo	ormance Evaluation	74
9.1 N	Monitoring, Measurement, Analysis & Evaluation	74
9.1.1	General	
9.1.2	Customer Satisfaction	
9.1.3	Analysis & Evaluation	76
9.1.4	Evaluation of Compliance	77
9.2 l	nternal Audit	77
9.2.1	Internal Audit Programme	78
9.2.2	Internal Audit Checklists	78
9.3 N	Management Review	80
9.3.1	General	
9.3.2	Inputs	
9.3.3	Outputs	
10 Imp	provement	83
10.1	General	83
10.2	Incident, Nonconformity & Corrective Action	
10.2.1		
10.2.2		
10.3	Continual Improvement	

ISO 9001:2015 & ISO 45001:2018

This team should consist of key individuals from various divisions, departments, and operating work areas from within your organization who are familiar with the facility and the various processes within. Diversity among team members will bring together a pool of expertise and ideas from which to develop and implement the HSQ management system.

One of the key moments in the implementation process is defining the individual responsibility of management and employees for the introduction of different elements into current working process.

That is why the most experienced employees from the company should be involved in this process.

Following this methodology, a team of experienced and engaged key personnel should be formed at the beginning of the implementation process.

The implementation team should include personnel that have the authority to devote resources to the project and to remove roadblocks.

The implementation team should meet on an 'as needed' basis according to the project timeline.

IMPROVEMENT

PERFORMANCE
EVALUATION

OPERATIONS

LEADERSHIP

PLANNING

SUPPORT

When the implementation team meets, they must address the items on their task list. Spread out the implementation team meetings along the implantation timeline so you do not have too many meetings at one time.

For example, you may want to have the document control team meet early in the project to establish a system to collect and control the documents that will be generated. Whereas, the internal audit team would meet later in the process because audits will not begin until the system is complete.

For certain activities, consulting organizations may provide expertise and guidance, which can be useful in the implementation of the HSQ management system. However, internal staff should be involved throughout the process because they will need to operate the HSQ management system on a daily basis.

2.4 Management Review Meetings

There are no specified time periods applicable to conducting management review meetings. However, they are essential during the initial development and implementation stages of the HSQ management system and should be conducted on an as-required basis.

There is a lot of merit in conducting management review meetings following internal and external audits, to review the findings and plan for follow-up/corrective actions. Some organizations may also find it beneficial to conduct a management review meeting prior to an external surveillance or certification audit, in order to identify gaps that can be filled prior to the external audit(s) being conducted.

It is important that a member of Top management chairs the management review meetings. The meetings provide useful insight into the basic processes and enable management to respond accordingly. It is imperative

ISO 9001:2015 & ISO 45001:2018

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 HSQ management system?' 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 and ISO 45001 this could be an additional process in the identification of 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 <u>Context & Interested Parties</u> <u>Matrix</u>. 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.

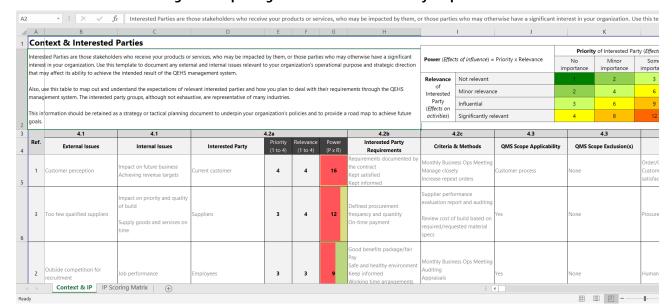


Figure 1: Capturing Context & Interested Party Requirements

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 <u>Context & Interested Parties Matrix</u> 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 registers, risk and opportunity registers, and legal and compliance registers.

ISO 9001:2015 & ISO 45001:2018

The <u>Context & Interested Parties Matrix</u> 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

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

Action Matrix

Score	Power of Interested Party (Effects on decisions)			
Score	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 HSQ management system, 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 and 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 HSQ management system.

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.

ISO 9001:2015 & ISO 45001:2018

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 your 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.

G H I J K L M N O P Q R **Process Responsibility Matrix** Management Operation Support The process matrix provides a very convenient up your management system. Defining the sequ 1. Enter process also a requirement. This process matrix itself can names Human Resources & Training After you're done populating this worksheet, c Production/Manufacturing Procurement & Supply Order/Quote Fulfillment in to the 'Process Matrix' worksheet in the QEHS Internal Audit Programme.xlsx iness Review & Improve nent Control & Knov Sales & Marketing ISO 14001:2015 Internal Audit Other 3 Other 2 Other 4 Other 5 Other 1 1. Enter the process/functional area names in Row 2, we've included examples to get 2. Enter an 'X' in the cell if the process has responsibility for ensuring conformity to clause(s) listed below 3. Using the 'filter' drop-down menu, select 'X' to show the applicable clauses for each 3. Filters Context of the Organization 3 4 4.1 Organizational Context 2. Enter an 'X' in 4.2 Relevant Interested Parties Management System Scope relevant cells HS Process Matrix Process Application (+)

Figure 2: Process Matrix Example

- 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.

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 integrated manual. Subsequently, this includes the actual and technical inputs and outputs of the processes to show their inter-relationship.

Use the <u>Process Application</u> 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 and ISO 45001:2018 Clause 4.4.

The completed <u>Process Matrix & Application</u> 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:

- 1. Identifying the processes needed for the HSQ management system, including their sequence and interaction;
- 2. Ensuring effective operation and control of the processes, e.g., defined process requirements, defined roles, required competencies, associated training or guidance material;

ISO 9001:2015 & ISO 45001:2018

- 3. Ensuring inputs and outputs from each of the identified processes, together with assignment of responsibilities and authorities e.g., process owner, Champions and process users;
- 4. Ensuring effective operation and control of the identified processes, e.g., process monitoring indicators, process performance indicators, target setting, data collection, performance trends and internal/external audit results.
- Demonstrating arrangements for process governance e.g., process owner reviews, process councils, flight deck/dashboards, risks and opportunities relating to the process, resource needs, user training/competency and continual improvement initiatives.

Process Application

4. Use this worksheet to map on thosy pror organization establishes, represents and continually improves its management system. It is allows personnel to dearly understands how your organization establishes, represents and interactions, in a continual progress and the readmap in the enteractions, in a continual progress and the process and the readmap to the enteractions and continually improves its management system in process and the interactions in a continual progress and the process and the proc

Figure 3: Process Application Example

4.4.3 Outsourced Processes

Outsourced processes must be controlled by the organization and these controls must be defined and described within their system. Organizations are required to identify the controls they apply for any outsourced processes. The integrated manual must identify if outsourced processes are applicable. In addition, written documentation on the methods used to control the outsourced processes. Examples of some outsourced processes are:

- 1. A process completed wholly or partially by a sister facility outside the scope of registration. Such as corporate performing design, purchasing or customer related processes, this includes management activities i.e., business planning, goal setting, resources, data analysis, budgeting, etc. This may include the entire element or a subsection i.e., corporate completes supplier evaluation and re-evaluation of suppliers and the registered site initiates purchase orders.
- 2. A process completed by an outside vendor or subcontractor such as heat treating, plating, calibration, painting, powder coating, etc. These types of processes may be controlled by the purchasing process where a formal contract or purchase order may be the controls. If this is the case, written documentation would be the purchasing documentation and records however; these processes are required to be documented.

If an outsourced process is controlled through purchasing, there must be documented objective evidence to ensure that these processes are being controlled beyond the basic purchasing requirements, which are focused on controlling products not processes. The organization is responsible to ensure that the outsourced process

ISO 9001:2015 & ISO 45001:2018

is meeting the applicable requirements to ISO 9001:2015. Outsourced processes may be controlled through such methods as, but not limited to:

- 1. Auditing;
- 2. Contractual agreements;
- 3. Process performance data review on an on-going basis;
- 4. Purchasing process.

Ensuring control over outsourced processes does not absolve the organization of the responsibility for conforming to customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

- 1. The potential impact of the outsourced process on the organization's capability to provide a product or service that conforms to requirements;
- 2. The degree to which the control of the process is shared;
- 3. The capability of achieving the necessary control through the application of the purchasing process.