

ISO High Level Standards (HSL)

4. Context of the organization	
Understanding the organization and its context	Have a look at your internal & external environment and figure out the key factors that impact on your organisation and how you might be able to influence or direct them
Understanding the needs and expectations of interested parties	Who's impacted by your organisation and what do they want from you?
Determining the scope of the quality management system	Which parts of your company are covered by your QMS/EMS/SMS/IMS? Which parts of the standard apply to your company?
Quality management system and its processes	This is about getting a practical understanding of the management, control and improvement of your processes.
5. Leadership	
Leadership and commitment	<p>The leadership team is accountable for the outcome of the management system.</p> <p>The policies and objectives must be consistent with the organisational strategy.</p> <p>The certified management system must be used to help manage the business.</p> <p>Advocate a process approach and ensure that everyone understands how risk impacts on the business.</p> <p>Ensure that the necessary resources are available.</p> <p>Communicate the importance of the management system and why it's critical that everyone conforms to its requirements.</p> <p>Make sure the management system produces the expected outcomes.</p> <p>Show leadership in getting employees involved in the management system.</p> <p>Encourage and support improvement activities.</p> <p>Assist other managers in showing leadership of the management system.</p>
Customer focus	<p>Top management must ensure that customer requirements and any applicable legislative and regulatory requirements are determined and met.</p> <p>Top management must ensure the risks and opportunities that might affect products, services and customer satisfaction are determined and acted upon.</p> <p>Top Management must ensure that the organisation focuses on creating customer satisfaction.</p>
Policy	<p>This is top management's overall direction and philosophy related to the QMS, EMS, SMS or IMS You can call it what you want – Mission Statement, Vision, Charter.</p> <p>It is a high level document which must originate from top management. It must be communicated to all relevant parties –</p>

	employees, stakeholders and it must be understood and utilised by the organisation
Organizational roles, responsibilities and authorities	Roles and authorities must be clearly documented so that everyone understands what needs to be done, and who is empowered to do what.
6. Planning	
Actions to address risks and opportunities	Risk is anything that can affect the organisation's ability to achieve its objectives. It can be good or bad.
Objectives and planning to achieve them	There must be clear objectives and there must be plans for how they will be achieved.
Planning of changes	Any changes that affect the organisation must be planned and the impact of those changes understood. This could include changes to the IT system, purchase of new equipment or hiring of additional employees. The emphasis is on significant changes – not the everyday changes or minor tweaks.
7. Support	
Resources	The organisation must have the necessary resources, people, systems & infrastructure to operate the business effectively.
Environment for the operation of processes	The organisation must provide a suitable environment for the effective operation of its processes.
Monitoring and measuring resources	The organisation is responsible for analysing its monitoring and measuring resources, understanding how they are used and determining what process will best indicate fitness for purpose.
Measurement traceability	If traceability back to some national or international standard is required then calibration of equipment will be necessary. If you need your resources to be accurate, calibration is the most logical process.
Organizational knowledge	The organisation must demonstrate that it has a process for retaining organisational knowledge and promoting organisational learning so that it can learn from its successes and failures in a sustainable way. This is really about ensuring that whatever knowledge exists within the organisation is readily available and understood. In an environment of constant change where employee retention is often lower than it used to be, the retention and access to organisational knowledge will become a more critical issue.
Competence	The organisation must define what specific competences are required for people to perform effectively. They must be realistic, demonstrable and forward-looking and maintained as documented information.
Awareness	Employees must be aware of, the quality/environmental/safety policy, the objectives that apply to their role and how they contribute to them.
Communication	The organisation must develop a communication strategy: <ul style="list-style-type: none"> ➤ What are we trying to communicate? ➤ When do we communicate? ➤ Who are we communicating with? ➤ How will we communicate? ➤ Who is the communication from?
Documented information	The organisation must maintain documented information through: Documents – living information that is used for decision making and subject revision.

	Records – historical information about things that have already happened.
8. Operation	
Operational planning and control	This is about how you establish, resource, and manage your production processes
Requirements for products and services	What requirements must your products & services satisfy?
Customer communication	You must have explicit channels of customer communication: <ul style="list-style-type: none"> ➤ Product information ➤ Enquiries & changes ➤ Feedback ➤ Customer property ➤ Contingency requirements
Determination of requirements related to products and services	Examples: <ul style="list-style-type: none"> ➤ Product or service description ➤ Performance requirements ➤ Price ➤ Quantity ➤ Timing ➤ Location of product or service delivery
Review of requirements related to products and services	Does the organisation understand the requirements and can we meet them?
Changes to requirements for products and services	When product requirements change. Make sure to amend the relevant documents. If you can't meet the requirements, don't accept the order.
Design and development of products and services	As a minimum you must meet the requirements in the design of products if you perform design. Before you state that you don't design ask yourself some questions: <ul style="list-style-type: none"> ➤ Do you produce a unique product or service for which your customer hasn't provided specifications? You may be doing design and development. ➤ If the customer has provided vague performance requirements and asked you to come up with a product or service, you may be doing design & development. ➤ If one or more of your products is protected by patents you may be doing design & development.
Design and development planning	The design plan is the route you expect to take in creating the design. <ul style="list-style-type: none"> ➤ What tasks will need to be undertaken? ➤ Who needs to take part? ➤ How long will the process take? ➤ What resources will be needed?
Design and development inputs	The inputs tell us what design & development must satisfy. <ul style="list-style-type: none"> ➤ Functional & performance requirements ➤ Information from previous designs ➤ Statutory & regulatory requirements ➤ Standards or codes ➤ Potential consequences of failure
Design and development controls	There are a number of elements covered under this area. <ul style="list-style-type: none"> ➤ Design & development review ➤ Purposes of design review ➤ Participants in design review ➤ Typical agenda ➤ Design and development verification ➤ Verification topics ➤ Responsibility for performing verifications

	<ul style="list-style-type: none"> ➤ Changes to the design ➤ Records of design verification ➤ Design & development validation ➤ Keys to successful validation ➤ Meeting requirements for specified application or intended use.
Design and development outputs	Design output is the product of the design process. It defines exactly what the organisation will produce to meet the design input requirements
Design and development changes	The organisation must identify, review and control any design changes by essentially going back through the entire design process.
Control of externally provided processes, products and services	<p>This is essentially what used to be called purchasing. It is the products & services you buy from another organisation – including an internal organisation. At minimum 3 categories must be managed and controlled through your purchasing process:</p> <ul style="list-style-type: none"> ➤ Raw materials ➤ Products or services that a supplier provides directly to your customer ➤ Processes provided by subcontractors <p>There may be other categories but it is up to the organisation to define the purchased products that have the greatest effect on your operations</p>
Type and extent of control	This requires the organisation to conduct a serious analysis of how external providers affect your success – and what you will do about it.
Information for external providers	You must tell your external providers exactly what you expect from them
Control of production and service provision	You must control the processes that produce your goods and services
Identification and traceability	<p>In nearly every organisation it will be necessary to maintain positive identification of all outputs:</p> <ul style="list-style-type: none"> ➤ Products ➤ Components ➤ Raw materials ➤ Processes ➤ Services
Property belonging to customers or external providers	<ul style="list-style-type: none"> ➤ Identify property ➤ Verify property ➤ Protect & safeguard property ➤ Property that is lost, damaged or found to be unsuitable
Preservation	<p>Your responsibility for preservation starts when you process the materials or products and continues until it is delivered.</p> <ul style="list-style-type: none"> ➤ Preservation during handling ➤ Preservation during packaging ➤ Preservation during storage
Post-delivery activities	<p>Post-delivery activities help move a sale away from a simple transaction and on towards a long-term relationship. Look at the following elements.</p> <ul style="list-style-type: none"> ➤ Statutory & regulatory requirements ➤ Potential problems ➤ Application & lifecycle ➤ Customer Requirements ➤ Customer Feedback
Control of changes	This is different from planning of changes in section 6. It relates more to “tactical” changes on the “shop floor” rather than long term strategic changes.

	<p>Documented information must be kept on:</p> <ul style="list-style-type: none"> ➤ Results of reviewing the changes ➤ Who authorised the change? ➤ Any necessary actions from the review?
Release of products and services	This is about checking before you release a product or service.
Control of nonconforming outputs	The purpose of controlling non-conforming outputs is to contain and minimise their effects. The system therefore will be defensive with its purpose being to contain problems and prevent them from reaching and/or affecting customers.
9. Performance evaluation	
Monitoring, measurement, analysis and evaluation	<p>You need to:</p> <ul style="list-style-type: none"> ➤ Determine what needs to be monitored & measured ➤ Identify methods for monitoring, measurement, analysis & evaluation ➤ Identify when the monitoring & measurement will be performed ➤ Identify when the results will be analysed and evaluated ➤ Evaluate the performance & effectiveness of the management system ➤ Retain documented information
Customer satisfaction	<p>You need to:</p> <ul style="list-style-type: none"> ➤ Monitor customers' perceptions ➤ Monitor the degree to which needs & expectations have been filled ➤ Determine methods for collecting & using feedback
Analysis and evaluation	<p>This requirement links back to the previous element "Monitoring, measurement, analysis and evaluation" which primarily looks at the monitoring and measurement aspects.</p> <p>We now need to look at analysis and evaluation across the following areas:</p> <ul style="list-style-type: none"> ➤ Conformity of products & services ➤ Customer Satisfaction ➤ Effectiveness of the management system ➤ Effectiveness of planning ➤ Action on risks & opportunities ➤ Performance of suppliers & subcontractors ➤ Need for improvements to the management system
Internal audit	<p>Conduct internal audits "at planned intervals"</p> <ul style="list-style-type: none"> ➤ Determine whether the system conforms to the organisation's own requirements and to that of the applicable standards. ➤ Determine whether the system is effectively implemented and maintained. ➤ Plan, establish, implement and maintain an audit programme ➤ Consider the importance of the processes, changes affecting the organisation, and results of previous audits. ➤ Develop audit criteria and scope for each audit. ➤ The audits must be objective and impartial. ➤ Report the results to management. ➤ Implement correction and corrective action. ➤ Retain documented information of the audit programme and results
Management review	The process by which top management reviews the performance of the system and analyses the performance of the organisation.
Management review input	<ul style="list-style-type: none"> ➤ The inputs are specified in the standards.

	<ul style="list-style-type: none"> ➤ The input is the information you receive.
Management review output	<ul style="list-style-type: none"> ➤ The outputs are specified in the standards. ➤ The output is what you do with the information you receive.
10. Improvement	
General	You must determine & select opportunities for improvement targeted at customer requirements & customer satisfaction
Nonconformity and corrective action	<p>Corrective action is the process for investigating and taking action on existing problems.</p> <p>Nonconformities are the trigger for corrective actions.</p> <p>You don't have to address every nonconformity but you must assess the risks and benefits and make a rational decision based on the following process:</p> <ul style="list-style-type: none"> ➤ Review and analyse nonconformities ➤ Determine the root cause ➤ Determine if similar nonconformities exist ➤ Implement actions ➤ Review effectiveness ➤ Update risks & opportunities ➤ Make any necessary changes to system <p>Corrective actions must be appropriate to the effects of the nonconformities identified.</p> <p>Retain documented information</p>
Continual Improvement	<p>Continual improvement is about becoming a more effective organisation.</p> <p>The improvement process should involve as many people in the organisation as possible</p>

A more detailed discussion of the concepts outlined above with many useful examples can be found in **ISO 9001:2015 in Plain English by Craig Cochran**. We have found this to be a very useful guide and recommend it to assist in coming to grips with the ISO language.

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