ISO 9001

Clauses

Issued 2026

Clause 1: Scope – The first clause details the scope of the standard.

Clause 2: Normative references – ISO 9000, *Quality management systems – Fundamentals and vocabulary*, is referenced and provides valuable guidance.

Clause 3: Terms and definitions – All the terms and definitions are contained in ISO 9000:2015 – *Quality management – Fundamentals and vocabulary*.

High-Level Structure (HLS)

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

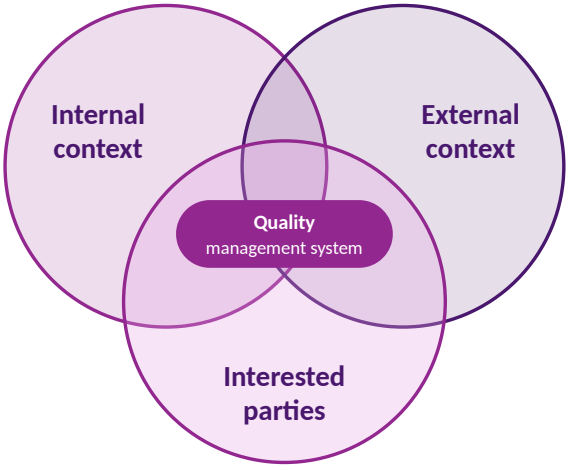
The ten-clause Annex SL structure shared by ISO 9001 and other ISO management system standards

Clause 4: Context of the organisation

This clause establishes the context of the Management System and how the business strategy supports this. “Context of the organisation” is the clause that underpins the rest of the standard. It gives an organisation the opportunity to identify and understand the factors and parties in their environment that support the Management System.

The starting point is to identify all external and internal issues relevant to your Management System. Then you need to establish all “interested parties” and how they are relevant to your Management System. The next step is to decide on the scope of your Management System. This may be the whole of your organisation or specific, identified functions. Finally, by using the process approach, you’ll need to show how you establish, implement, maintain and continually improve the Management System in relation to the standard.

Clause 4	Clause number
Understanding the organisation and its context	4.1
Understanding the needs and expectations of interested parties	4.2
Determining the scope of the quality management system	4.3
Quality management system and its processes	4.4



Understanding the context of the organisation

Clause 5: Leadership

This clause is all about the role of "top management", the group of people who direct and control your organisation at the highest level. They need to ensure that the Management System and its requirements are integrated into the organisation's processes and that the policy and objectives are aligned with the strategic direction of the organisation. They also need to make sure that the Management System is made available, communicated, maintained and understood by all parties.

There's also a focus on customer satisfaction, and top management need to show how this is enhanced. They will also need to show the organisation's internal strengths and weaknesses and how they could have an impact on products or services. They need to understand the key risks associated with each process and the approach taken to manage, reduce or transfer the risk. Top management can assign Management System responsibilities and authorities but, ultimately, they remain accountable for it.

Clause 5	Clause number
Leadership (title only)	5
Leadership and commitment	5.1
General	5.1.1
Customer focus	5.1.2
Quality policy	5.2
Establishing the quality policy	5.2.1
Communicating the quality policy	5.2.2
Organisational roles, responsibilities and authorities	5.3

Clause 6: Planning

This clause focuses on how an organisation plans actions to address both risks and opportunities. Consideration of risks needs to be proportionate to the potential impact they may have, and opportunities could include new product launches or geographical expansion, for example.

Actions to address risks and opportunities must be monitored, managed and communicated across the organisation. Another key area of this clause is the need to establish measurable quality objectives. Finally, this clause covers what is referred to as "planning of changes". This must be done in a systematic manner – for example, organisations should consider who is involved, when changes are to take place and the potential consequences of change.

Clause 6	Clause number
Planning (title only)	6

Clause 6	Clause number
Actions to address risks and opportunities	6.1
Quality objectives and planning to achieve them	6.2
Planning of changes	6.3

Clause 7: Support

This section of ISO 9001 is all about getting the right resources, the right people and the right infrastructure in place to meet the organisational goals. Organisations should make sure that resources are made available to do this. It could include making training and personnel available, for example.

Organisational knowledge relating to the Management System is also covered in this clause. Personnel must not only be aware of the quality policy, they must also understand how they contribute to it and what the implications of not conforming are. This is where the term "documented information" is referred to.

Previous versions of ISO 9001 required a quality manual; the standard no longer stipulates this. It does, however, require organisations to determine the level of documented information that's necessary to control the Management System. There's also an emphasis on controlling access to documented information, which reflects the importance of information security.

Clause 7	Clause number
Support (title only)	7
Resources	7.1
General	7.1.1
People	7.1.2
Infrastructure	7.1.3
Environment for the operation of processes	7.1.4
Monitoring and measuring resources	7.1.5
General	7.1.5.1
Measurement traceability	7.1.5.2
Organisational knowledge	7.1.6
Competence	7.2
Awareness	7.3
Communication	7.4
Documented information (title only)	7.5
General	7.5.1
Creating and updating	7.5.2
Control of documented information	7.5.3

Clause 8: Operation

This clause is all about the execution of the plans and processes that enable an organisation to meet customer requirements. It acknowledges the increased use of outsourced and subcontracted functions, and there is a requirement to establish criteria for monitoring the performance of these parties in addition to keeping records used to establish selection criteria.

This clause also covers “requirements for products and services”. There is a requirement for communicating with potential customers, which could be useful when developing new solutions for the market. Finally, there is a section which covers post-delivery activities, which could include maintenance or repair. Organisations need to consider the risks associated with a product or service, customer requirements, customer feedback and any statutory requirements.

Clause 8	Clause number
Operational planning and control	8.1
Requirements for products and services	8.2
Customer communication	8.2.1
Determining the requirements for products and services	8.2.2
Review of the requirements for products and services	8.2.3
Changes to the requirements for products and services	8.2.4
Design and development of products and services	8.3
General	8.3.1
Design and development planning	8.3.2
Design and development inputs	8.3.3
Design and development controls	8.3.4
Design and development outputs	8.3.5
Design and development changes	8.3.6
Control of externally provided processes, products and services	8.4
General	8.4.1
Type and extent of control	8.4.2
Information for external providers	8.4.3
Production and service provision	8.5

Clause 8	Clause number
Control of production and service provision	8.5.1
Identification and traceability	8.5.2
Property belonging to customers or external providers	8.5.3
Preservation	8.5.4
Post-delivery activities	8.5.5
Control of changes	8.5.6
Release of products and services	8.6
Control of nonconforming outputs	8.7

Clause 9: Performance evaluation

This is all about measuring and evaluating your Management System to ensure that it is effective, and it helps you to continually improve. You will need to consider what should be measured, the methods employed, and when data should be analysed and reported on.

Organisations must also actively seek out information on customer perception of their products or services – for example, through satisfaction surveys. Internal audits will need to be carried out, and there are certain "audit criteria" defined to ensure that the results of these audits are reported to relevant management. Finally, management reviews will need to be carried out and "documented information" must be kept as evidence.

Clause 9	Clause number
Performance evaluation (title only)	9
Monitoring, measurement, analysis and evaluation	9.1
General	9.1.1
Customer satisfaction	9.1.2
Analysis and evaluation	9.1.3
Internal audit	9.2
Management review	9.3
General	9.3.1
Management review inputs	9.3.2
Management review outputs	9.3.3

Clause 10: Improvement

This clause requires organisations to determine and identify opportunities for continual improvement of the Management System. There is a requirement to actively look out for opportunities to improve processes, products or services, particularly with future customer requirements in mind.

There are some actions that are required that cover the handling of corrective actions. Firstly, organisations need to react to the nonconformities and take action. Secondly, they need to identify whether similar nonconformities exist or could potentially occur.

Clause 10	Clause number
Improvement (title only)	10
General	10.1

Clause 10	Clause number
Nonconformity and corrective action	10.2
Continual improvement	10.3