ISO 9001:2015
Quality Management System

Course Code	ISO 9001:2015 – QMS
Format	Fully Self-Paced Online (4–6 hours of study and practice per unit)
Level	Intermediate (Foundation → Implementer / Internal Auditor Readiness)
Assessment	Final Online Examination (Multiple-choice + Short Essays)
Certificate	Certificate of Completion
Sectors Covered	Manufacturing, Services, Healthcare, Construction, Public Sector
Edition	Revised edition, October 2026 (see Revision Notes, Appendix E)

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Learning Outcomes

By the end of this course, participants will be able to:

1. Explain the structure, intent and interrelationships of all clauses of ISO 9001:2015 and the seven Quality Management Principles.
2. Apply the process approach, the PDCA cycle and risk-based thinking to real organisational contexts.
3. Conduct a gap analysis against ISO 9001:2015 requirements.
4. Develop practical process maps, risk and opportunity registers, a quality policy, quality objectives and essential documented information.
5. Plan, conduct, report and follow up internal audits in accordance with ISO 19011 principles.
6. Prepare an organisation for a certification body Stage 1 and Stage 2 audit.
7. Identify common nonconformities and formulate effective corrective actions.

Course Map

Unit	Subject	Clauses	Main practical outputs
1	Foundations of quality management	1–3	Principles-in-practice analysis
2	Context of the organisation	4	Context analysis, interested parties matrix, QMS scope, process map
3	Leadership	5	Quality policy draft, RACI matrix
4	Planning	6	Risk and opportunity register, SMART objectives, change plan
5	Support	7	Competence matrix, document control procedure outline, calibration register
6	Operation, part 1	8.1–8.3	Core process maps, customer requirements review checklist
7	Operation, part 2	8.4–8.7	Supplier evaluation criteria, nonconformity control form
8	Performance evaluation	9	Internal audit programme, management review agenda
9	Improvement and implementation	10	Root cause analysis, mini gap analysis, corrective action process
10	Audit skills and certification preparation	ISO 19011	Nonconformity statements, audit checklist

Unit 1 – Foundations of Quality Management & ISO 9001:2015

This opening unit establishes the conceptual foundation required for all subsequent learning. Without a clear grasp of what quality management means, how the discipline evolved, and the architecture of the ISO 9000 family, the detailed requirements of Clauses 4–10 cannot be interpreted or applied with precision.

1.1 Quality, Quality Control, Quality Assurance and Quality Management

ISO 9000:2015 defines quality as "the degree to which a set of inherent characteristics of an object fulfils requirements." In organisational practice this means the consistent ability to meet stated and implied needs of customers and other relevant interested parties.

Three related but distinct concepts must be differentiated. In ISO 9000 terms, **quality control** is the part of quality management focused on fulfilling quality requirements; in practice it is the inspection, testing and measurement that detects defects. **Quality assurance** is the part focused on providing confidence that quality requirements will be fulfilled; in practice it is the planned, systematic prevention built into processes, procedures and competence. **Quality management** is broader still: it encompasses the coordinated activities that direct and control an organisation with regard to quality, including quality policy and objectives, planning, control, assurance and improvement within a coherent system.

ISO 9001 is a quality management system standard. Its requirements go well beyond inspection and traditional assurance activities. An organisation that merely inspects finished product or follows a set of procedures is not, by that fact alone, operating a quality management system in the sense required by the standard.

1.2 Evolution of Quality Thinking

Contemporary quality management rests on intellectual foundations laid throughout the twentieth century. W. Edwards Deming emphasised systems thinking, statistical process control, the Plan-Do-Check-Act cycle and the responsibility of leadership. Joseph M. Juran formulated the quality trilogy of planning, control and improvement and popularised the Pareto principle in quality contexts. Philip B. Crosby advanced the concepts of "zero defects" and "quality is free," arguing that the cost of poor quality far exceeds the cost of prevention. Kaoru Ishikawa contributed the cause-and-effect diagram and the practice of quality circles. Total Quality Management later integrated these ideas into an organisation-wide philosophy.

ISO 9001:2015 absorbs many of these contributions particularly the process approach, leadership accountability, evidence-based decision making, and continual improvement into a structured, auditable framework that can be applied by organisations of any size or sector. Research on the implementation of ISO 9001:2015 has identified a range of drivers, benefits and barriers experienced by organisations (Bravi, Murmura & Santos, 2019)

1.3 History and Evolution of ISO 9001

The standard itself has developed through several editions, each responding to how organisations actually used the previous one.

Year	Edition or event	Main development
1979	BS 5750	The British Standards Institution publishes a national standard for quality assurance systems, the forerunner of ISO 9001.
1987	First ISO 9000 series	ISO publishes ISO 9001, 9002 and 9003 as three models for quality assurance, chosen according to the scope of the organisation's activities.
1994	Second edition	A revision that keeps the three-model structure and strengthens requirements on preventive action.
2000	Third edition	A major revision. The three models merge into a single ISO 9001. The process approach, customer satisfaction and continual improvement become central, supported by quality management principles.
2008	Fourth edition	Clarifications to the 2000 text, with no new requirements.
2015	Fifth edition	Adoption of the High-Level Structure (Annex SL). Introduces context, risk-based thinking, stronger leadership requirements, organisational knowledge and the term "documented information". Seven quality management principles.
2024	Amendment 1:2024	Adds climate change considerations to Clauses 4.1 and 4.2.
2026	Sixth edition	ISO 9001:2026 published on 16 September 2026, replacing ISO 9001:2015 after a three-year transition (see the notice at the start of this manual).

1.4 The ISO 9000 Family

The core standards of the family are ISO 9000 (fundamentals and vocabulary), ISO 9001 (requirements), ISO 9004 (guidance for sustained success) and ISO 19011 (guidelines for auditing management systems). Only ISO 9001 contains requirements against which an organisation may be certified. The other standards support understanding, improvement and the conduct of audits.

1.5 The Seven Quality Management Principles

Multi-country empirical research confirms that organisations adopt ISO 9001:2015 for both external reasons (customer pressure, market access) and internal reasons (process improvement and organisational performance) (Fonseca et al., 2019). ISO 9000:2015 and ISO 9001:2015 are underpinned by seven quality management principles. These principles are not themselves auditable requirements, yet they inform the entire structure and intent of the standard. They are: customer focus; leadership; engagement of people; process approach; improvement; evidence-based decision making; and relationship management.

Each principle has direct operational implications. Customer focus requires that the organisation understands and meets customer requirements and strives to enhance satisfaction. Leadership requires that top management creates and maintains the internal environment in which people can become fully involved. Engagement of people recognises that competent, empowered and engaged people at all levels are essential. The process approach treats activities as interrelated processes that function

as a coherent system. Improvement must be a permanent objective. Decisions should be based on the analysis and evaluation of data. Relationships with relevant interested parties, including external providers, influence performance and should be managed accordingly.

1.6 High-Level Structure, Process Approach, PDCA and Risk-based Thinking

Since the 2015 revision, ISO 9001 follows the High-Level Structure (Annex SL) common to all ISO management system standards. The ten-clause structure (Scope, Normative references, Terms and definitions, Context of the organisation, Leadership, Planning, Support, Operation, Performance evaluation, Improvement) facilitates integration with other management system standards.

The process approach requires the organisation to determine the processes needed for the QMS, their sequence and interactions, the criteria and methods for effective operation and control, the resources needed, and the assignment of responsibilities. The PDCA cycle provides the underlying logic for managing processes and the system as a whole: Plan (establish objectives and processes), Do (implement), Check (monitor and measure), Act (improve). Risk-based thinking replaces the freestanding preventive action clause of earlier editions. The organisation is required to determine risks and opportunities that could affect the ability of the QMS to achieve its intended results, and to plan proportionate actions. This thinking is applied throughout the system rather than confined to a single clause. The 2015 edition places greater emphasis on risk-based thinking, leadership and the process approach, reflecting a shift toward value creation and organisational performance (Fonseca & Domingues, 2017).

1.7 Key Terminology Changes from the 2008 Edition

Several terms changed in the 2015 revision. “Products” became “products and services.” “Documents” and “records” were unified under the single term “documented information,” distinguished only by whether the information is maintained (kept up to date) or retained (kept as evidence). The role of management representative ceased to be mandatory. The quality manual ceased to be mandatory. “Exclusions” were replaced by the more rigorous concept of non-applicability, which must be justified. “Purchasing” was broadened to “control of externally provided processes, products and services.” These changes are not merely semantic; they reflect a deliberate shift toward greater flexibility and stronger emphasis on process performance and risk.

Practical Activity and Self-Check

> **Practical 1: Quality principles in practice**
>
> Read the scenario: *A components manufacturer has lost two customers this year. Deliveries are late about three times in ten. The managing director looks at quality only when a customer complains. Operators learn of specification changes from colleagues. Suppliers are chosen on price alone and never reviewed.*
>
> For each of the seven principles, state whether the scenario shows it applied or neglected and quote the evidence. Then write one action that would strengthen each neglected principle.

Sector lens: manufacturing. Repeated late deliveries and informal change control are typical symptoms of weak process control and weak customer focus.

Suggested reading: Fonseca and Domingues (2017); Bravi, Murmura and Santos (2019); ISO 9000:2015.

Self-check

1. Explain the difference between quality control and quality assurance in one sentence each.
2. Which edition of ISO 9001 merged ISO 9001, 9002 and 9003 into a single standard?
3. Why did ISO 9001:2015 remove the separate preventive action clause?
4. Which of the ISO 9000 family standards can an organisation be certified to?

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Unit 2 – Clause 4: Context of the Organisation

Clause 4 requires the organisation to understand itself and its operating environment before designing or operating a quality management system. The clause supplies the foundation for subsequent planning, operational control and improvement. Amendment 1:2024 added an explicit obligation to determine whether climate change is a relevant issue. Studies of ISO 9001:2015 adoption across different countries highlight the importance of understanding organisational context when designing the QMS (Fonseca et al., 2019).

4.1 Understanding the Organisation and its Context

The organisation shall determine external and internal issues that are relevant to its purpose and strategic direction and that affect its ability to achieve the intended results of the QMS. The organisation shall also determine whether climate change is a relevant issue.

Internal issues typically include organisational culture, structure, values, knowledge, resources, and the performance of existing processes. External issues are commonly analysed through frameworks such as PESTLE (Political, Economic, Social, Technological, Legal, Environmental). Climate-related issues may appear as physical risks (extreme weather, resource scarcity), transition risks (regulatory change, carbon pricing, shifting customer expectations), or opportunities (new markets for lower-impact products or services).

The requirement does not compel every organisation to adopt a climate action plan. It requires the organisation to determine whether climate change is a relevant issue. In practice an auditor will expect to see how that determination was reached, whichever way it went. Where climate change is found relevant, the resulting risks and opportunities should be considered in planning under Clause 6.1 and, where appropriate, in operational controls and objectives.

4.2 Understanding the Needs and Expectations of Interested Parties

The organisation shall determine the interested parties that are relevant to the QMS, the requirements of those interested parties that are relevant to the QMS, and which of those requirements will be addressed through the QMS. A note added by Amendment 1:2024 records that relevant interested parties can have requirements related to climate change.

An interested party is any person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity of the organisation. Relevance is determined by the potential impact on the organisation’s ability to provide conforming products and services or to enhance customer satisfaction. Typical relevant interested parties include customers, employees, external providers, regulators, owners or shareholders, and, in some contexts, the local community or society at large.

4.3 Determining the Scope of the Quality Management System

The scope defines the boundaries and applicability of the QMS. When establishing the scope the organisation must consider the external and internal issues identified under 4.1, the requirements of relevant interested parties under 4.2, and the products and services of the organisation. The scope shall be maintained as documented information and shall state the types of products and services

covered. Any requirement of the standard determined to be not applicable must be justified; non-applicability cannot be claimed merely for convenience.

4.4 Quality Management System and its Processes

The organisation shall establish, implement, maintain and continually improve a QMS, including the processes needed and their interactions. For each process the organisation must determine inputs and expected outputs, sequence and interaction, criteria and methods for effective operation and control, resources needed, responsibilities and authorities, risks and opportunities, and arrangements for evaluation and improvement. Documented information must be maintained to the extent necessary to support the operation of processes and retained to the extent necessary to have confidence that the processes are being carried out as planned.

Practical Activity and Self-Check

> **Practical 2: Context, scope and process map**
>
> Choose a real organisation (or one of the Unit 9 mini-cases). Produce four items:
>
> 1. A context analysis listing at least five internal and five external issues (use SWOT or PESTLE) and a note on whether climate change is relevant and why.
> 2. An interested parties matrix with columns: party, relevant requirements, how the QMS addresses them.
> 3. A one-paragraph QMS scope statement that names the products and services, locations and any requirement judged not applicable with its justification.
> 4. A high-level process map showing core, management and support processes and how they connect.

Sector lens: healthcare. For a hospital laboratory, patients, referring clinicians, regulators and funders are all interested parties with different requirements, and the scope must say which services (for example collection, testing, reporting) fall inside the QMS.

Suggested reading: Bravi and Murmura (2022) on implementation in organisations of different sizes; Fonseca et al. (2019).

Self-check

1. What must an organisation be able to show about climate change under Clause 4.1?
2. Why can an organisation not claim a requirement is non-applicable merely for convenience?
3. Name three interested parties and one relevant requirement for each.
4. What must be determined for each process under Clause 4.4?

Unit 3 – Clause 5: Leadership

Clause 5 places accountability for the quality management system squarely on top management. The 2015 revision removed the mandatory management representative role, making leadership commitment non-delegable in principle. Effective leadership commitment has been identified as a critical success factor in the transition to and maintenance of ISO 9001:2015 (Fonseca & Domingues, 2017).

5.1 Leadership and Commitment

Top management shall demonstrate leadership and commitment by taking accountability for the effectiveness of the QMS; ensuring that the quality policy and objectives are established and compatible with the context and strategic direction; ensuring the integration of QMS requirements into business processes; promoting the process approach and risk-based thinking; ensuring that necessary resources are available; communicating the importance of effective quality management and of conforming to QMS requirements; ensuring that the QMS achieves its intended results; engaging, directing and supporting persons to contribute to the effectiveness of the QMS; promoting improvement; and supporting other relevant management roles to demonstrate leadership in their areas of responsibility.

Customer focus forms a specific aspect of this commitment. Top management must ensure that customer and applicable statutory and regulatory requirements are determined, understood and consistently met; that risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; and that the focus on enhancing customer satisfaction is maintained.

5.2 Policy

Top management shall establish, implement and maintain a quality policy that is appropriate to the purpose and context of the organisation and supports its strategic direction; provides a framework for setting quality objectives; includes a commitment to satisfy applicable requirements; and includes a commitment to continual improvement of the QMS. The policy shall be maintained as documented information, be communicated, understood and applied within the organisation, and be available to relevant interested parties as appropriate.

5.3 Organisational Roles, Responsibilities and Authorities

Top management shall ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood. Specific responsibility and authority must be assigned for ensuring that the QMS conforms to the requirements of the standard; ensuring that processes deliver their intended outputs; reporting on the performance of the QMS and on opportunities for improvement, particularly to top management; ensuring the promotion of customer focus throughout the organisation; and ensuring that the integrity of the QMS is maintained when changes are planned and implemented. These responsibilities may be distributed among several persons; what matters is that they are clearly assigned and understood.

Practical Activity and Self-Check

Practical 3: Quality policy and RACI matrix

1. Draft a quality policy of no more than 100 words for your organisation. Check it against the four requirements of 5.2: appropriate to purpose and context, framework for objectives, commitment to satisfy requirements, commitment to continual improvement.

2. Complete a RACI matrix (R responsible, A accountable, C consulted, I informed) for the QMS roles in your organisation, using the example below as a model.

QMS activity	Top mgmt	Quality lead	Process owners	HR	All staff
Quality policy	A	R	C	I	I
Quality objectives	A	R	R	C	I
Risk and opportunity register	A	R	R	C	I
Competence and training	I	C	R	A	I
Internal audit programme	A	R	C	I	I
Management review	A/R	R	C	C	I
Corrective actions	I	A	R	C	C

Sector lens: public sector. Service charters and accountability to citizens can support the policy, but top management must still own the QMS even when authority is layered across departments.

Suggested reading: Psomas and Pantouvakis (2015).

Self-check

1. Why is leadership commitment described as non-delegable?
2. List the four content requirements of a quality policy.
3. Does ISO 9001:2015 require a management representative? What must be assigned instead?
4. How should a quality policy be communicated and made available?

Unit 4 – Clause 6: Planning

Planning converts the understanding of context and the commitments of leadership into concrete actions, objectives and change controls. Clause 6 is the point at which risk-based thinking becomes operational.

6.1 Actions to Address Risks and Opportunities

When planning for the QMS, the organisation shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed in order to give assurance that the QMS can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects, and achieve improvement. The organisation shall plan actions to address these risks and opportunities, plan how to integrate and implement the actions into QMS processes, and plan how to evaluate the effectiveness of the actions. Actions shall be proportionate to the potential impact on the conformity of products and services.

ISO 9001 does not require a formal risk-management system conforming to ISO 31000, nor does it mandate a documented risk procedure. The method used to determine and address risks and opportunities may be simple or elaborate according to the organisation's context, size and complexity. What is required is that the determination takes place, that actions are planned and implemented, and that effectiveness is evaluated.

6.2 Quality Objectives and Planning to Achieve Them

The organisation shall establish quality objectives at relevant functions, levels and processes. The objectives shall be consistent with the quality policy, measurable, take into account applicable requirements, be relevant to conformity of products and services and to enhancement of customer satisfaction, be monitored, be communicated, and be updated as appropriate. Documented information on the quality objectives shall be maintained. When planning how to achieve its quality objectives, the organisation shall determine what will be done, what resources will be required, who will be responsible, when it will be completed, and how the results will be evaluated.

6.3 Planning of Changes

When the organisation determines the need for changes to the QMS, the changes shall be carried out in a planned manner. The organisation shall consider the purpose of the changes and their potential consequences, the integrity of the QMS, the availability of resources, and the allocation or reallocation of responsibilities and authorities. Uncontrolled change is a frequent source of nonconformity and loss of system integrity.

Practical Activity and Self-Check

Practical 4: Risk register, objectives and change plan

1. Build a risk and opportunity register for two processes in your organisation, using the columns shown below.

2. Convert the quality policy from Practical 3 into three SMART objectives (specific, measurable, achievable, relevant, time-bound), each with what, resources, who, when and how it will be evaluated.

3. Write a one-page change plan for one QMS change (for example, introducing a new supplier evaluation process): purpose, consequences, effect on QMS integrity, resources, responsibilities.

Process	Risk or opportunity	Effect	Prob. (1–5)	Impact (1–5)	Action	Owner and date	Effectiveness check
Delivery	Late materials delay dispatch	Late deliveries, lost customers	4	4	Add second supplier; safety stock	Purchasing, June	On-time delivery above 95%
Site works	Heavy rain interrupts concrete pours	Schedule and quality loss	3	4	Weather plan and covers	Site manager, May	Pours rejected for weather: zero
Design	Opportunity: reuse approved design modules	Faster design, fewer errors	3	3	Create module library	Design lead, Sept	Design review rework down 20%

Sector lens: construction. Weather, subcontractor delays, design changes and safety-critical quality risks are the usual starting points for a project risk register.

Suggested reading: ISO 31000:2018 for background on risk management (not required by ISO 9001); risk-based thinking papers in Appendix B.

Self-check

1. What does Clause 6.1 require beyond identifying risks and opportunities?
2. Does ISO 9001 require a documented risk procedure? Explain.
3. List the five things to determine when planning how to achieve objectives.
4. Why is uncontrolled change a risk to the QMS?

Unit 5 – Clause 7: Support

Clause 7 addresses the resources, competence, awareness, communication and documented information necessary for the QMS to function. Without adequate support, even well-designed processes will fail to deliver consistent results.

7.1 Resources

The organisation shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS, taking into account the capabilities of and constraints on existing internal resources and what needs to be obtained from external providers. Specific attention is required for people, infrastructure, the environment for the operation of processes, monitoring and measuring resources, and organisational knowledge.

7.1.5 Monitoring and measuring resources

Where monitoring or measurement is used to show that products and services conform, the organisation must provide the resources needed to get valid and reliable results. These resources must be suitable for the type of monitoring or measuring being done and must be maintained so they stay fit for their purpose. The organisation retains documented information as evidence that the resources are fit for purpose.

Where measurement traceability is a requirement, or is considered by the organisation to be an essential part of confidence in results, measuring equipment must be calibrated or verified (or both) at specified intervals, or before use, against measurement standards that are traceable to international or national standards. Where no such standard exists, the basis used for calibration or verification must be retained as documented information. The equipment must also be identified so its calibration status can be determined, and safeguarded from adjustments, damage or deterioration that would invalidate the result.

If measuring equipment is found unfit for its purpose, the organisation must determine whether the validity of earlier measurement results has been adversely affected and take appropriate action. In practice this means identifying which products, services or decisions relied on the equipment since its last valid calibration.

> **Why 7.1.5 matters for audits**
> Calibration gaps are among the most common certification findings: instruments missing from the register, calibration overdue, no record of the standard used, and no review of earlier results.

Calibration register field	Example
Instrument ID and description	M-014, outside micrometer 0–25 mm
Location and user	Final inspection, QC technician
Calibration interval	12 months
Last calibration and next due	Last 12 March; due 12 March next year
Reference standard and certificate	Gauge blocks set GB-02, certificate 2291, traceable to national standard

7.1.6 Organisational knowledge

Organisational knowledge is the knowledge specific to the organisation that is necessary for the operation of its processes and for achieving conformity of products and services. It is to be maintained and made available to the extent necessary. When addressing changing needs and trends the organisation shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

The organisation shall determine the necessary competence of persons doing work under its control that affects the performance and effectiveness of the QMS; ensure that these persons are competent on the basis of appropriate education, training or experience; where applicable take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken; and retain appropriate documented information as evidence of competence.

7.3 Awareness and 7.4 Communication

Persons doing work under the organisation's control shall be aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the QMS (including the benefits of improved performance), and the implications of not conforming with QMS requirements. The organisation shall also determine the internal and external communications relevant to the QMS, including on what it will communicate, when, with whom, how, and who communicates. Transition studies indicate that competence development and awareness of the new requirements are frequently underestimated during implementation (Fonseca & Domingues, 2018).

7.5 Documented Information

The QMS shall include documented information required by ISO 9001 and documented information determined by the organisation as necessary for the effectiveness of the QMS. When creating and updating documented information the organisation shall ensure appropriate identification and description, format and media, and review and approval for suitability and adequacy. Documented information shall be controlled to ensure it is available and suitable for use where and when needed, and adequately protected. Control activities include distribution, access, retrieval and use; storage and preservation; control of changes; and retention and disposition. Documented information retained as evidence of conformity shall be protected from unintended alterations.

A critical distinction is maintained between documented information that is maintained (documents that are kept up to date) and documented information that is retained (records that provide evidence of results achieved or activities performed).

Practical Activity and Self-Check

Practical 5: Competence matrix, document control and calibration register

1. Build a competence matrix for one department: roles down the side, required competences across the top, and a rating or date for each person. Mark gaps and plan training.

2. Outline a documented information control procedure covering identification, format, review and approval, distribution, storage, change control, retention and disposal.

3. Create a calibration register for ten instruments using the fields in the table above (or, for a service organisation, justify why 7.1.5 applies to few or no instruments).

Person	Role	Competence 1: sample inspection	Competence 2: use of micrometer	Competence 3: record keeping	Action
A. Otieno	QC technician	Competent (assessed Jan)	Competent (assessed Jan)	Competent	None
B. Wanjiru	QC technician	In training	Not assessed	Competent	Assess by March

Sector lens: services and healthcare. In services, competence (7.2) and knowledge (7.1.6) usually matter more than equipment. Healthcare and manufacturing both need 7.1.5 for thermometers, loggers and gauges.

Suggested reading: Wilson and Campbell (2020) on quality management and knowledge management.

Self-check

1. What must be done when measuring equipment is found out of calibration?
2. What is the difference between maintained and retained documented information?
3. Name two ways to provide evidence of competence.

Unit 6 – Clause 8: Operation (Part 1)

Clause 8 contains the requirements for the operational processes that produce products and services. Part 1 addresses operational planning and control, the determination and review of requirements for products and services, and design and development.

8.1 Operational Planning and Control

The organisation shall plan, implement and control the processes needed to meet requirements for the provision of products and services and to implement the actions determined in Clause 6. This includes determining the requirements for products and services; establishing criteria for the processes and for the acceptance of products and services; determining the resources needed; implementing control of the processes in accordance with the criteria; and determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services. Planned changes shall be controlled and the consequences of unintended changes reviewed, with action taken to mitigate adverse effects as necessary. Outsourced processes remain within the organisation's control.

8.2 Requirements for Products and Services

The organisation shall establish processes for communicating with customers regarding products and services information, enquiries, contracts or order handling (including changes), customer feedback (including complaints), handling or controlling customer property, and specific requirements for contingency actions when relevant. When determining the requirements for products and services to be offered, the organisation shall ensure that the requirements are defined (including applicable statutory and regulatory requirements and those considered necessary by the organisation) and that the organisation can meet the claims it makes. Before committing to supply, the organisation shall review the requirements, including those specified by the customer, those not stated by the customer but necessary for specified or intended use, those specified by the organisation, applicable statutory and regulatory requirements, and any contract or order requirements differing from those previously expressed. Differences shall be resolved. Documented information describing the results of the review and any new requirements shall be retained. Changes to requirements shall result in amendment of relevant documented information and awareness of the changed requirements by relevant persons.

8.3 Design and Development of Products and Services

Where the organisation designs or develops products or services, a design and development process appropriate to ensure subsequent provision shall be established, implemented and maintained. Planning shall consider the nature, duration and complexity of the activities; required process stages including reviews; required verification and validation activities; responsibilities and authorities; internal and external resource needs; control of interfaces; involvement of customers and users; requirements for subsequent provision; the level of control expected by customers and other relevant interested parties; and the documented information needed. Inputs shall be determined, complete, unambiguous and free of conflict. Controls shall ensure that results to be achieved are defined, that reviews, verification and validation are conducted, that necessary actions are taken on problems, and that documented information is retained. Outputs shall meet input requirements, be adequate for

subsequent processes, include or reference monitoring and measuring requirements and acceptance criteria, and specify characteristics essential for intended purpose and safe and proper provision. Changes shall be identified, reviewed and controlled to the extent necessary to ensure no adverse impact on conformity; documented information on changes, reviews, authorisation and actions shall be retained.

Where design and development is not performed, the organisation may determine that Clause 8.3 is not applicable, provided the justification is recorded in the scope (Clause 4.3).

Practical Activity and Self-Check

Practical 6: Process map and customer requirements review

1. Map one core operational process from customer request to delivery. Show inputs, outputs, activities, resources, controls, acceptance criteria and where records are kept.

2. Create a customer requirements review checklist, using the items below as a start, and apply it to one real or sample order.

- [ ] Requirements specified by the customer are recorded and understood
- [ ] Requirements not stated but needed for intended use are identified
- [ ] Statutory and regulatory requirements are identified
- [ ] The organisation’s own requirements are included
- [ ] Differences from earlier contract or order terms are resolved
- [ ] The organisation has the capacity and competence to meet the requirements
- [ ] Results of the review and any new requirements are recorded
- [ ] Changes to requirements are communicated to the people affected

Sector lens: manufacturing and construction. Manufacturing design and development covers new products. In construction, design changes after contract award are a frequent source of nonconformity, so Clause 8.3 change control and 8.2 review of changed requirements both apply.

Suggested reading: Sá et al. (2022) on integrating ISO 9001 with Lean Six Sigma.

Self-check

1. When may an organisation determine that Clause 8.3 is not applicable?
2. What must be reviewed before committing to supply a product or service?
3. What is the difference between design verification and validation?
4. Which parts of 8.2 and 8.3 require documented information to be retained?

Unit 7 – Clause 8: Operation (Part 2)

Part 2 of Clause 8 addresses control of external provision, production and service provision under controlled conditions, release of products and services, and control of nonconforming outputs.

8.4 Control of Externally Provided Processes, Products and Services

The organisation shall ensure that externally provided processes, products and services conform to requirements. Controls shall be applied when products and services from external providers are intended for incorporation into the organisation's own products and services, when products and services are provided directly to the customer by external providers on behalf of the organisation, or when a process or part of a process is provided by an external provider as a result of a decision by the organisation. Criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers shall be determined and applied. Documented information of these activities and of any necessary actions arising from evaluations shall be retained. The type and extent of control shall take into account the potential impact on the organisation's ability to consistently meet customer and applicable statutory and regulatory requirements, and the effectiveness of the controls applied by the external provider. Requirements shall be communicated to external providers before they are relied upon, covering the processes, products and services to be provided; approval of products and services, methods, processes, equipment and release; competence; interactions with the organisation; control and monitoring of performance; and verification or validation activities to be performed by the organisation or its customer at the external provider's premises. Effective control and development of external providers contributes to the ability of the organisation to deliver conforming products and services consistently (Fonseca & Lima, 2015)

8.5 Production and Service Provision

Production and service provision shall be implemented under controlled conditions. Controlled conditions include, as applicable, the availability of documented information defining characteristics of products or services and the results to be achieved; the availability and use of suitable monitoring and measuring resources; the implementation of monitoring and measurement activities at appropriate stages; the use of suitable infrastructure and environment; the appointment of competent persons; the validation and periodic revalidation of processes where the resulting output cannot be verified by subsequent monitoring or measurement; the implementation of actions to prevent human error; and the implementation of release, delivery and post-delivery activities. Outputs shall be identified when necessary to ensure conformity. The status of outputs with respect to monitoring and measurement requirements shall be identified. When traceability is a requirement, unique identification shall be controlled and documented information retained. Property belonging to customers or external providers shall be identified, verified, protected and safeguarded; loss, damage or unsuitability shall be reported and documented. Outputs shall be preserved to the extent necessary to ensure conformity. Post-delivery activities shall meet applicable requirements, taking into account statutory and regulatory requirements, potential undesired consequences, the nature, use and intended lifetime of the products and services, customer requirements and customer feedback. Changes for production or service provision shall be reviewed and controlled; documented information describing the results of the review, the person authorising the change and any necessary actions shall be retained.

8.6 Release of Products and Services

Planned arrangements shall be implemented at appropriate stages to verify that product and service requirements have been met. Release shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Documented information on the release shall be retained and shall include evidence of conformity with acceptance criteria and traceability to the person(s) authorising the release.

8.7 Control of Nonconforming Outputs

Outputs that do not conform to their requirements shall be identified and controlled to prevent unintended use or delivery. Appropriate action shall be taken based on the nature of the nonconformity and its effect on conformity of products and services; this applies also to nonconforming products and services detected after delivery or during or after the provision of services. Nonconforming outputs shall be dealt with by one or more of the following: correction; segregation, containment, return or suspension of provision; informing the customer; obtaining authorisation for acceptance under concession. Conformity shall be verified when nonconforming outputs are corrected. Documented information shall be retained that describes the nonconformity, the actions taken, any concessions obtained, and the authority deciding the action in respect of the nonconformity.

Practical Activity and Self-Check

> **Practical 7: Supplier evaluation and nonconformity control**
>
> 1. Draft supplier evaluation criteria and a scoring sheet for selection, performance monitoring and re-evaluation, using the example below as a model.
>
> 2. Design a nonconformity control form that captures the fields required by 8.7: description, how found, actions taken (correction, segregation, return, concession), who authorised, and verification after correction.

Criterion	Weight	Score 1–5	Evidence
Quality of delivered goods or services (defect or rework rate)	30%		Receiving inspection records
On-time delivery	25%		Delivery log
Competence and certifications relevant to the work	20%		Certificates, audit report
Responsiveness to problems and complaints	15%		Corrective action records
Price and commercial terms	10%		Contract

Sector lens: healthcare and construction. A hospital that outsources reference laboratory testing and a contractor that relies on subcontractors both remain responsible for the outsourced result. Competence evidence and communication of requirements before reliance (8.4.3) are common audit questions.

Suggested reading: Fonseca and Lima (2015) on supplier management strategies and organisational performance.

Self-check

1. When does Clause 8.4 apply to an external provider?
2. List four ways nonconforming outputs may be dealt with.
3. What documented information must be retained when a product is released?
4. When must a process be validated and periodically revalidated?

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Unit 8 – Clause 9: Performance Evaluation

Clause 9 closes the "Check" stage of the PDCA cycle. It requires the organisation to determine what to monitor and measure, to conduct internal audits, and to review the QMS at planned intervals so that top management can decide whether the system remains suitable, adequate and effective.

9.1 Monitoring, Measurement, Analysis and Evaluation

The organisation shall determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, when the monitoring and measuring shall be performed, and when the results shall be analysed and evaluated. The performance and effectiveness of the QMS shall be evaluated. Appropriate documented information shall be retained as evidence of the results.

Customer satisfaction shall be monitored. The organisation shall determine the methods for obtaining, monitoring and reviewing information on customers' perceptions of the degree to which their needs and expectations have been fulfilled. Methods commonly include surveys, complaint and compliment analysis, direct feedback, retention or repeat-business data, and warranty or returns information.

Appropriate data and information arising from monitoring and measurement shall be analysed and evaluated. The results shall be used to evaluate conformity of products and services, the degree of customer satisfaction, the performance and effectiveness of the QMS, whether planning has been implemented effectively, the effectiveness of actions taken to address risks and opportunities, the performance of external providers, and the need for improvements to the QMS.

9.2 Internal Audit

Internal audits shall be conducted at planned intervals to provide information on whether the QMS conforms to the organisation's own requirements and to the requirements of ISO 9001, and whether it is effectively implemented and maintained. An audit programme shall be planned, established, implemented and maintained, taking into consideration the importance of the processes concerned, changes affecting the organisation, and the results of previous audits. Audit criteria and scope shall be defined for each audit. Auditors shall be selected and audits conducted to ensure objectivity and impartiality. Results shall be reported to relevant management. Appropriate correction and corrective actions shall be taken without undue delay. Documented information shall be retained as evidence of the implementation of the audit programme and of the audit results.

ISO 19011 provides guidance on the principles of auditing, the management of an audit programme, and the conduct of audits. Although ISO 9001 does not require a documented internal audit procedure, most organisations find such a procedure useful for ensuring consistency.

9.3 Management Review

Top management shall review the QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organisation. The review shall take into consideration the status of actions from previous management reviews; changes in external and internal issues relevant to the QMS; information on the performance and effectiveness of the QMS (including trends in customer satisfaction and feedback from relevant interested parties, the extent to which quality objectives have been met, process performance and conformity of products

and services, nonconformities and corrective actions, monitoring and measurement results, audit results, and the performance of external providers); the adequacy of resources; the effectiveness of actions taken to address risks and opportunities; and opportunities for improvement. Outputs shall include decisions and actions related to opportunities for improvement, any need for changes to the QMS, and resource needs. Documented information shall be retained as evidence of the results of management reviews.

Practical Activity and Self-Check

> **Practical 8: Audit programme and management review**
>
> 1. Design a one-year internal audit programme for your organisation: list every process, assign a frequency based on importance, recent changes and previous results, name auditors who are independent of the area, and set audit criteria and scope.
>
> 2. Write a management review agenda that covers every input listed in 9.3 and a template for recording decisions on improvement, QMS changes and resource needs.

Process	Risk and change	Last audit result	Frequency	Auditor	Quarter
Order handling	High: customer-facing	2 minor	Twice a year	Quality lead	Q1, Q3
Purchasing	High: supplier issues	1 major (closed)	Twice a year	Finance auditor	Q2, Q4
Training	Medium	None	Yearly	Operations auditor	Q3
Document control	Medium: new software	1 observation	Yearly	Quality lead	Q2

Sector lens: public sector and services. Citizen satisfaction surveys, complaint analysis and service level figures are typical inputs to 9.1 and 9.3; unreviewed figures are a common audit finding.

Suggested reading: Kafetzopoulos, Psomas and Gotzamani (2015) on ISO 9001 effectiveness as the extent to which quality objectives are met.

Self-check

1. What three things must the audit programme take into consideration?
2. List five inputs to management review.
3. What outputs must a management review produce?
4. Name four methods of monitoring customer satisfaction.

Unit 9
Clause 10: Improvement and the Implementation Roadmap

Clause 10 requires the organisation to determine and select opportunities for improvement and to implement necessary actions. It distinguishes correction from corrective action and places a continuing obligation on the organisation to improve the suitability, adequacy and effectiveness of the QMS.

Clause 10.1 General

The organisation shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include improving products and services to meet requirements as well as to address future needs and expectations; correcting, preventing or reducing undesired effects; and improving the performance and effectiveness of the QMS.

Clause 10.2 Nonconformity and Corrective Action

When a nonconformity occurs, including any arising from complaints, the organisation shall react to the nonconformity and, as applicable, take action to control and correct it and deal with the consequences. The organisation shall evaluate the need for action to eliminate the cause(s) of the nonconformity in order that it does not recur or occur elsewhere, by reviewing and analysing the nonconformity, determining the causes, and determining if similar nonconformities exist or could potentially occur. Any action needed shall be implemented. The effectiveness of any corrective action taken shall be reviewed. Risks and opportunities determined during planning shall be updated if necessary, and changes to the QMS shall be made if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered. Documented information shall be retained as evidence of the nature of the nonconformities and any subsequent actions taken, and of the results of any corrective action.

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Correction is action to eliminate a detected nonconformity (for example, rework, replacement, or re-performance of a service). Corrective action is action to eliminate the cause of a nonconformity in order to prevent recurrence. The two are sequential but distinct. Not every nonconformity requires extensive root-cause analysis; the depth of investigation and the extent of corrective action must be proportionate to the effects of the nonconformity.

Clause 10.3 Continual Improvement

The organisation shall continually improve the suitability, adequacy and effectiveness of the QMS. The organisation shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement. Continual improvement is not confined to corrective action after nonconformities; it includes proactive enhancement of processes, products, services and the system itself.

9.4 Root Cause Analysis Tools

Clause 10.2 requires the organisation to determine the causes of a nonconformity so that it does not recur. The depth of analysis should match the effect of the nonconformity: a one-off labelling slip needs less than a recurring late-delivery problem.

Tool	Use it when	How it works
5 Whys	One failure with a likely single chain of cause	Ask why repeatedly (usually three to five times) until you reach a cause the organisation can control
Fishbone (Ishikawa)	Several possible causes need sorting	Group causes under branches such as people, method, machine, material, measurement and environment (add policy and place for services)
Pareto analysis	Many problem types and limited effort	Count or cost each problem type and rank them; a few types usually account for most of the effect

Worked example (services). A customer was invoiced twice. Why? The order was entered twice. Why? The first entry showed an error message, so the agent re-entered it. Why? The system saved the order despite the error. Why? The error message appears before the save finishes and is not clear. Why? The software supplier was never asked to review the message in testing. *Correction:* credit the customer. *Corrective action:* fix the message and add a duplicate-order check. *Effectiveness review:* count duplicate orders for three months.

9.5 Implementation Roadmap

The roadmap below suits an organisation building its first QMS. Timing depends on size, resources and how much already works well, so the phases show order and outputs rather than durations.

Phase	Main activities	Key output
1. Commit	Top management decides, assigns a project lead and resources, agrees why the organisation wants the QMS	Project charter
2. Understand	Determine context, interested parties and scope (Clause 4)	Context analysis, interested parties register, scope statement
3. Assess	Run a gap analysis against the standard (see 9.6)	Gap analysis report
4. Plan	Set the quality policy, objectives, risk and opportunity register (Clauses 5 and 6)	Policy, objectives plan, risk register, project plan
5. Design	Map processes, define controls, create only the documented information the standard or the organisation needs	Process maps, procedures where useful, forms
6. Implement	Raise awareness, train, run the processes and keep records	Operating processes, records
7. Check	Complete a full cycle of internal audits and hold a management review with all required inputs	Audit reports, management review minutes

Phase	Main activities	Key output
8. Improve	Correct nonconformities, analyse causes, close actions	Corrective action records
9. Certify	Choose an accredited certification body, then Stage 1 and Stage 2 audits	Certification decision
10. Sustain	Surveillance audits, objectives review, continual improvement	Maintained and improving QMS

Common implementation mistakes: copying another company's manual instead of describing how the organisation actually works; writing more documented information than the work needs; leaving top management out of the project; scheduling the certification audit before the processes have produced records; setting a scope wider than the organisation can evidence.

9.6 Gap Analysis Method

A gap analysis compares current practice with each requirement of ISO 9001:2015 and records what is missing, how serious it is and what to do about it.

1. Set the scope and criteria: ISO 9001:2015 with Amendment 1:2024, plus the organisation's own requirements and applicable legal requirements.
2. Gather evidence by reading documents and records, interviewing people and watching processes run. A procedure on a shelf is not evidence that the process works.
3. Rate each requirement on the scale below.
4. Record the evidence you saw, so a second assessor reaches the same rating.
5. Prioritise gaps by risk to the customer and to certification, then by effort.
6. Write the action plan with owners and dates.
7. Reassess after actions close.

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Rating	Meaning
0	Not in place
1	Partly in place: informal, inconsistent or undocumented where documentation is required
2	In place with minor gaps
3	Fully in place, working and evidenced

Worked example. The example organisation is a 60-person precision machining company.

Clause	Requirement in brief	Evidence seen	Score	Gap and action	Priority
4.3	Scope maintained as documented information	No scope statement; website lists three services, shop floor offers two more	0	No documented scope. Draft and approve scope with top management	High

Clause	Requirement in brief	Evidence seen	Score	Gap and action	Priority
5.2	Quality policy documented, communicated	Policy shown in reception only; two operators could not state it	1	Not communicated. Brief all staff; add to induction	Medium
6.1	Risks and opportunities determined, actions planned	Informal discussion at weekly meeting, no record	1	No record. Build risk register with process owners	High
6.2	Measurable objectives, monitored	Objectives for on-time delivery and scrap tracked monthly	3	None. Keep reviewing at management review	Low
7.1.5	Calibrated or verified measuring equipment with traceability	Register covers calipers but not three torque wrenches	2	Three instruments missing. Add to register; calibrate	High
8.4	Control of external providers, evaluation and re-evaluation	Approved supplier list; no evaluation records for two years	1	No re-evaluation evidence. Define criteria; evaluate top ten suppliers	High
9.2	Audit programme and results retained	One audit last year covered four of ten processes; no programme document	1	Incomplete coverage. Write programme; train two auditors	High
9.3	Management review with all required inputs	Annual minutes lack audit results and external provider performance	2	Missing inputs. Use standard agenda with every 9.3 input	Medium
10.2	Nonconformity handled with cause analysis and effectiveness review	Corrections recorded; no causes or effectiveness checks	1	Corrective action incomplete. Introduce corrective action form	High

9.7 Corrective Action Process

1. Record the nonconformity: what, where, when, who found it, evidence.
2. Contain and correct it, and deal with the consequences (rework, replace, inform the customer).

3. Analyse the cause with 5 Whys, fishbone or Pareto, and check whether similar nonconformities exist or could occur.
4. Decide whether corrective action is needed, then plan it with an owner and date.
5. Implement the action.
6. Review whether the action worked, after enough time to see a result.
7. Update the risk and opportunity register and the QMS if needed.
8. Close the record and retain it as documented information.

Practical Activity and Self-Check

Practical 9: Mini gap analysis, corrective action and sector mini-cases

1. Mini gap analysis. Choose ten clauses from 4 to 10, rate them for your own organisation (or one of the cases below) on the 0 to 3 scale, and record the evidence for each rating.

2. Corrective action. Take one gap and write a corrective action record following the eight steps above.

3. Sector mini-cases. For each case, list the clauses affected and the first action you would take.

Sector	Facts	Clauses to consider
Manufacturing	Customers report dimension errors; some gauges have no calibration label; operators learn by watching colleagues	7.1.5, 7.2, 8.7, 10.2
Services (IT support)	Service level targets missed for three months; no one reviews the figures; the staff handbook dates from 2019	7.5, 9.1, 9.3, 10.1
Healthcare (diagnostic laboratory)	Reference testing is outsourced with no evaluation of the provider; sample labelling errors occurred twice	8.4, 8.5.2, 8.7
Construction	Design changes agreed by email; no record of customer approval; subcontractor competence never checked	7.2, 8.2.4, 8.3.6, 8.4
Public sector (licensing office)	No stated objectives; complaints logged but not analysed; approval authority unclear	5.3, 6.2, 9.1.3

Successful adoption is more likely when top management is actively involved and when the standard is used as a framework for real process improvement rather than solely for certification (Fonseca et al., 2019).

Self-check

1. Why is a gap analysis rating based on evidence rather than on the existence of a procedure?
2. What should an organisation have in place before inviting a certification body, and why?
3. Give one example of a correction and the corrective action that follows it.

4. Which root cause tool would you use for a problem with many possible causes, and why?
5. Name two common mistakes that make a first QMS fail at audit.

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Unit 10: Audit Skills, Certification Preparation & Final Review

This final unit consolidates the knowledge acquired in Units 1–9 and develops the practical skills required to write nonconformity statements, distinguish types of findings, understand the certification process, and prepare for both the final examination and real-world audit or implementation support.

10.1 Writing Nonconformity Statements

A nonconformity statement must be factual, precise and traceable. The conventional structure comprises three elements: the requirement (the specific clause of ISO 9001 or the organisation's own documented information that has not been met); the evidence (the objective evidence observed or examined during the audit); and the statement of nonconformity (a clear explanation of how the evidence demonstrates that the requirement has not been fulfilled). Opinion, speculation and vague language are to be avoided. The statement should enable a reader who was not present at the audit to understand exactly what was wrong and why it constitutes a nonconformity.

10.2 Classification of Findings

A major nonconformity is a serious failure that raises significant doubt about the ability of the QMS to achieve its intended results, or a complete absence of a required system element, or a collection of related minor nonconformities that indicate systemic failure. A minor nonconformity is a failure to meet a requirement that does not indicate a systemic problem. An observation is a statement of fact that does not constitute a nonconformity but may become one if not addressed. An opportunity for improvement is a suggestion for enhancing effectiveness or efficiency where the requirement is already met. Certification bodies require that major nonconformities be effectively addressed before certification is granted or continued.

> **Note on classification**
> ISO 9001 itself does not define major or minor nonconformity. These categories come from certification practice (certification bodies work under ISO/IEC 17021-1), and exact definitions and response timeframes vary by certification body. Internal audit programmes usually define their own categories. Always check the scheme you are working under.

10.3 Stage 1 and Stage 2 Certification Audits

Initial certification is normally conducted in two stages. Stage 1 reviews the organisation's documented information, its understanding of requirements, the context and scope of the QMS, and the status of internal audits and management review, in order to determine readiness for Stage 2. Stage 2 evaluates the implementation and effectiveness of the QMS and seeks objective evidence that processes are operating as planned and that the requirements of ISO 9001 are being met in practice. Successful completion of Stage 2 leads to a recommendation for certification. Thereafter the organisation is subject to surveillance audits (typically annual) and a recertification audit every three years.

10.4 Common Nonconformities and Certification Readiness

Recurring themes in certification audits include inadequate determination or treatment of risks and opportunities; quality objectives that are not measurable or not monitored; incomplete or ineffective

internal audits; management reviews that omit required inputs or fail to produce clear decisions and actions; weak control of external providers; inadequate control of nonconforming outputs; insufficient evidence of competence; poorly controlled documented information; and calibration or traceability gaps in measuring equipment. Before inviting a certification body, an organisation should ensure that the scope is accurate, that at least one full cycle of internal audits has been completed, that a management review covering all required inputs has been conducted, that known nonconformities have been addressed, that personnel are aware of the quality policy and objectives and of their contribution to the QMS, and that monitoring and measurement data have been analysed and are available.

10.5 Sustaining the System

Certification is not an end state. The value of a QMS lies in its continued operation as a living system that supports consistent conformity, customer satisfaction and improvement. Organisations that treat the QMS as a set of documents prepared for audit rather than as the way the organisation actually works frequently experience declining performance and recurring nonconformities at surveillance audits. Organisations that treat the QMS primarily as a documentation exercise rather than a management system tend to realise fewer benefits (Bravi, Murmura & Santos, 2019). Leadership commitment, competent people, risk-based thinking, process control, and genuine use of data for decision-making remain the conditions for sustained effectiveness.

10.6 Auditing Under ISO 19011:2018: Principles and Types

ISO 19011:2018 lists seven principles that make auditing a reliable way to find out whether a system works.

Principle	In practice
Integrity	Auditors work honestly, competently and without letting pressure change what they report
Fair presentation	Findings, conclusions and reports truthfully reflect what happened, including any disagreement
Due professional care	Auditors apply care and judgment in proportion to the importance of the task
Confidentiality	Information gained in the audit is protected and not used for personal gain
Independence	Auditors are impartial and free from bias, and do not audit their own work
Evidence-based approach	Conclusions rest on verifiable evidence from a sample, not on opinion
Risk-based approach	Audit effort goes to the matters that matter most for the objectives

- **First-party (internal) audits:** the organisation audits itself, as Clause 9.2 requires.
- **Second-party audits:** a customer audits a supplier, or an organisation audits an external provider.
- **Third-party audits:** an independent certification body audits for certification (Stage 1, Stage 2, surveillance, recertification).

10.7 Audit Programme and Audit Plan

The **audit programme** is the set of audits arranged for a period. Clause 9.2 requires the programme to consider the importance of the processes concerned, changes affecting the organisation and the results of previous audits, and requires auditors to be selected so that the audit is objective and impartial. An **audit plan** describes one audit: objectives, scope, criteria (for example ISO 9001:2015 and the organisation's own procedures), dates, locations, the audit team, the schedule and the people to be interviewed.

10.8 The Audit Process

Stage	What happens	Output
1. Initiating	Fix objectives, scope and criteria; confirm the audit is feasible; select the team	Audit objectives and scope
2. Preparing	Review documented information; write the audit plan; prepare checklists and working papers	Audit plan, checklist
3. Conducting	Hold the opening meeting; collect and verify evidence; generate findings; reach conclusions; hold the closing meeting	Findings and conclusions
4. Reporting	Issue the report to the audit client and relevant management	Audit report
5. Follow-up	The audited area corrects and takes corrective action; the programme verifies it	Closed findings

Opening meeting: confirm scope, plan, methods, who will guide, confidentiality, and how findings will be classified and reported. **Closing meeting:** present findings and conclusions clearly enough that the auditee understands them, agree a timeframe for responses, and note any disagreement.

10.9 Collecting Evidence

Audit evidence must be verifiable. Auditors gather information by **interview** (ask people what they do, using open questions such as how, what and show me, and avoiding leading questions), by **observation** (watch the process and its environment) and by **document and record review** (check procedures, records and data against what is actually done). Evidence from one source should be corroborated by another where the point matters. If an operator says the gauge is calibrated, look at the label and the register.

Sampling. An auditor cannot examine everything. Choose a sample that represents the whole: different shifts, products, projects, sites and people. State what was sampled in the report so a finding can be repeated.

Trace the audit trail. Follow one item through the system. For one customer order: enquiry and review of requirements (8.2); design or planning (8.3, where applicable); external providers used (8.4); production or service delivery under controlled conditions (8.5); release (8.6); complaints or nonconformities arising (8.7, 10.2). This shows whether the processes link up in practice and often exposes gaps that auditing clause by clause misses.

10.10 Auditing Processes, Not Departments

Turtle element	Question to ask
Inputs	What starts this process, and how do you know the input is right?
Outputs	What does the process produce, and who receives it?
Resources	What people, equipment and environment does it need?
Methods	What procedure or instruction guides the work, and how do you know it is followed?
Competence	Who does this work and how do you know they are competent?
Measures	How do you know the process is performing, and what is done when it is not?

10.11 Sample Checklist Questions

A checklist is a guide, not a script. Good auditors follow the evidence.

Clause	Question	Evidence to look for
4.1	How do you know which issues affect your QMS?	Context analysis, review records, climate change determination
4.3	What is your QMS scope?	Documented scope, justification for any non-applicability
5.2	Can you tell me the quality policy and what it means for your job?	Policy, staff understanding, communication records
6.1	What risks and opportunities have you identified, and what did you do?	Register or other records, actions, effectiveness review
6.2	What are your objectives and how are you doing against them?	Measurable objectives, monitoring results, plans
7.1.5	How do you know this measuring instrument is accurate?	Calibration or verification records, traceability
7.2	How do you know this person is competent for this task?	Competence records, training, evaluation
8.4	How did you choose and check this supplier?	Evaluation criteria and records, re-evaluation results
8.7	What happens when you find a nonconforming product or service?	Identification, segregation, concession records
9.2	Show me your audit programme and last audit results	Programme, reports, follow-up of findings
9.3	Show me the last management review	Minutes covering every input, decisions and actions
10.2	Show me a recent corrective action	Cause analysis, action, effectiveness review

10.12 Writing Audit Findings: Worked Examples

Every finding records the **requirement**, the **evidence** and a **statement** that links the two.

Weak: “Calibration is poor.”

Strong. *Requirement:* ISO 9001:2015 clause 7.1.5.2 requires measuring equipment to be calibrated or verified at specified intervals against traceable standards where traceability is required. *Evidence:* final inspection micrometer M-014 carried a calibration label that had expired 14 months before the audit; the calibration register showed no later record; the inspection records for the previous month, three of three sampled, used this instrument. *Statement:* the organisation did not ensure that M-014 was calibrated or verified at the specified interval, and used it to accept product.

Clause	Evidence	Statement
9.3.2	The latest management review minutes did not include audit results or the performance of external providers	The management review did not consider all required inputs
6.1	When asked, top management and the quality coordinator could produce no record of risks and opportunities or of actions taken	The organisation did not determine risks and opportunities or plan actions to address them
8.4.1	Three of five sampled suppliers had no evaluation record, although the supplier procedure requires evaluation before first use	The organisation did not apply its own criteria for evaluating external providers

An observation states a fact that is not yet a nonconformity but may become one: the calibration register is kept on a spreadsheet that two people can edit without version control. **An opportunity for improvement** suggests a way to do better where the requirement is already met: add the due date to the instrument label as well as the register.

10.13 Stage 1 and Stage 2 in More Detail

Aspect	Stage 1	Stage 2
Purpose	Check readiness and plan Stage 2	Judge whether the QMS is implemented and effective
Reviews	Documented information, scope, understanding of requirements, status of internal audit and management review, resources for Stage 2	Evidence of processes in operation against ISO 9001 and the organisation’s own requirements
Typical findings	Areas of concern that could become nonconformities at Stage 2	Nonconformities and areas for improvement
Outcome	Go or no-go for Stage 2, with concerns listed	Recommendation for certification once any nonconformities are addressed

After certification, surveillance audits take place at least annually and a recertification audit takes place before the certificate expires, normally every three years.

10.14 Certification Readiness Checklist

- [ ] Scope matches what the organisation really does and is documented
- [ ] Top management can explain the policy, objectives and its own role
- [ ] Risks and opportunities are determined and actions are recorded
- [ ] Required documented information exists and is controlled
- [ ] Measuring equipment is calibrated or verified where needed
- [ ] External providers are evaluated and re-evaluated
- [ ] A full cycle of internal audits covering every process is complete
- [ ] A management review with all required inputs has been held, with decisions and actions
- [ ] Nonconformities from audits have causes analysed and effectiveness reviewed
- [ ] Staff understand the policy, their objectives and their contribution
- [ ] An accredited certification body is chosen and Stage 1 is scheduled
- [ ] The certification body has confirmed which edition (2015 or 2026) the audit will use

Practical Activity and Self-Check

Practical 10: Nonconformity statements and audit checklist

1. Write a requirement, evidence and statement for each snippet below, then compare with the model answers.

2. Pick one process from your organisation and write ten checklist questions using the turtle diagram headings.

3. Trace one order, project or case from enquiry to delivery and note where each link in the audit trail is evidenced.

	Sector	Evidence snippet
A	Services	The complaints log shows 23 complaints this quarter with no cause or action recorded. The organisation’s procedure requires a cause analysis for every complaint
B	Construction	A concrete supplier used on Site 3 has no evaluation record. The organisation’s rule is to evaluate suppliers before first use
C	Healthcare	Two of five phlebotomists sampled have no competence assessment record since joining
D	Public sector	The quality objective is “improve citizen service”, with no target and no monitoring

Model answers

	Clause	Statement
A	10.2.1 and the organisation’s complaints procedure	The organisation did not analyse the causes of complaints or record any action, contrary to its own procedure
B	8.4.1	The organisation did not apply its criteria for the evaluation of an external provider before it was used

	Clause	Statement
C	7.2	The organisation did not retain evidence that two persons doing work affecting QMS performance are competent
D	6.2.1	Quality objectives are not measurable or monitored

Sector lens: all five sectors. Audit evidence in the snippets comes from services, construction, healthcare and the public sector; the worked findings above come from manufacturing.

Suggested reading: ISO 19011:2018 and ISO/IEC 17021-1 (the standard certification bodies work under).

Self-check

1. Name the seven audit principles and explain how the evidence-based approach affects the way you sample.
2. What is the difference between an audit programme and an audit plan?
3. Why should auditors follow an audit trail as well as a checklist?
4. What three things must a nonconformity statement connect?
5. How does a Stage 1 audit differ from a Stage 2 audit?

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