



IQCS Certification
IRCA (UK) Approved Auditor Training Organisation

Summary of changes between ISO 9001:2008 and ISO/DIS 9001:2015

Contents

Summary of changes between ISO 9001:2008 and ISO/FDIS 9001:2015	3
Annex B – Quality Management Principles	28
Terms and Definitions	29





New Clause No and Title

1 Scope

Existing Clause No

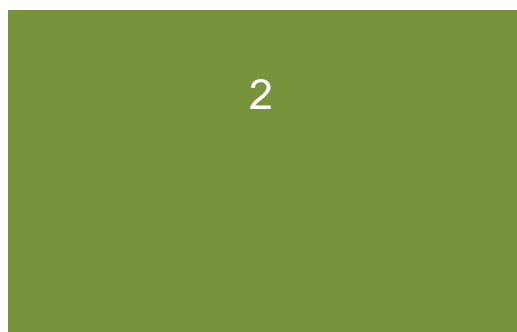


Summary of Changes

'Product' becomes 'product or service'
Note 1 b) Has been removed
1.2 Application, removed

2 Normative References

Existing Clause No



Summary of Changes

There are no normative references – clause has been included to maintain numbering alignment



New Clause No and Title

3 Terms & Definitions

Existing Clause No

3

Summary of Changes

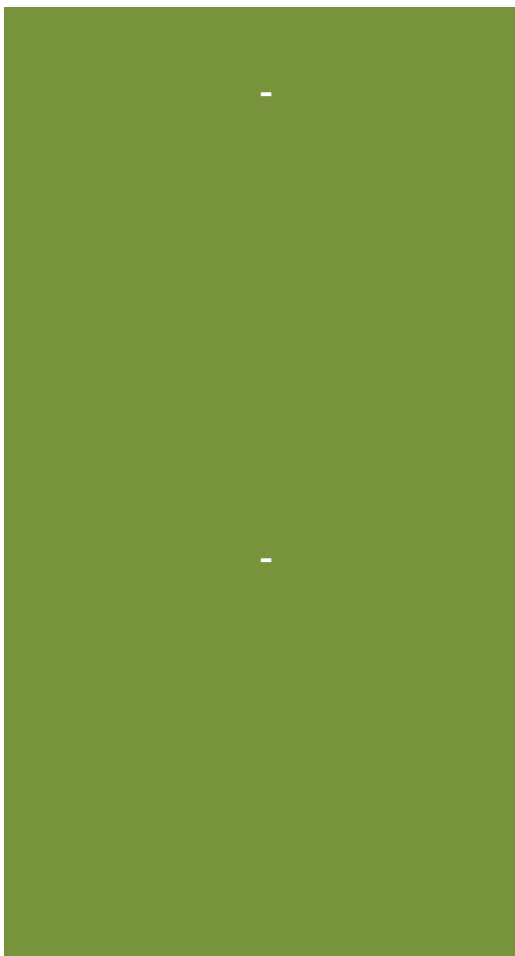
A list of common definitions included but may be removed later and put into ISO 9000:2015



New Clause No and Title

4 Context of the Organisation

Existing Clause No



Summary of Changes

4.1 Understanding the organisation and its context – new clause

This is a new requirement in which the organisation is required to demonstrate that it understands what influences there are on it with regard to both internal and external issues and may affect its strategic direction e.g. where it sits in the marketplace and what effect changes may have on its future.

4.2 Understanding the needs and expectations of interested parties – new clause

This is a new requirement and it requires the organisation ensure that their products and services meet customer and applicable statutory and regulatory requirements. They must identify who the interested parties are and monitor and review the information.



New Clause No and Title

4 Context of the Organisation

Existing Clause No

4

Summary of Changes

4.3 Determining the scope of the quality management system.

This is now a stated requirement of the standard and requires the organisation to determine the boundaries and applicability of the QMS. It also makes reference to 4.1 – (the context of the organisation), 4.2 (the interested parties) and the products and services of the organization.

There is a statement regarding the application of all the clauses within the scope of the standard being applied and for a justification for any exclusions being made (previously under permissible exclusions).



New Clause No and Title

4 Context of the Organisation

Existing Clause No

4.1

Summary of Changes

4.4 Quality management system and its processes

Still a requirement establish, implement, etc. a QMS.

The content is largely the same as the existing clause 4.1 apart from assigning responsibilities and authorities for the processes, and a requirement to determine the risks and opportunities. Whilst there is no specific mention of documented procedures, it does state that the organisation shall maintain documented information to the extent necessary to support the operation of the processes and to retain documented information to have confidence that processes are working as planned.



New Clause No and Title

5 Leadership

Existing Clause No

5

5.1

Summary of Changes

5.1 Leadership and commitment

5.1.1 Leadership and commitment for the quality management system

This is a new clause title but it contains much of what is currently in section 5, it. There is a requirement for top management to take accountability for the effectiveness of the QMS; demonstrate leadership and commitment with respect to the QMS e.g. ensuring the policy and objectives are compatible with the strategic direction, the policy is understood and followed, the QMS is integrated into the organisation's business processes; promote awareness of the process approach and improvement etc.



New Clause No and Title

5 Leadership

Existing Clause No

5.2

5.3

Summary of Changes

5.1.2 Customer focus

This relates to demonstrating leadership and commitment to customers – there are additional requirements based on the need to determine statutory and regulatory requirements which are applicable; the risks and opportunities are determined and addressed; the focus is on consistently providing conforming product to customers and focussing on enhancing customer satisfaction.

5.2 Quality policy

Largely unchanged from current version but does have some additional requirements about its availability to relevant interested parties and being available as documented information.



New Clause No and Title

5 Leadership

Existing Clause No

5.5

Summary of Changes

5.3 Organisational roles, responsibilities and authorities

Small changes to existing requirements and whilst it has removed the explicit requirement for the appointment of a management representative, the activities that person undertook are still there.

In addition to the previous requirements, it has added 'ensuring that the processes are delivering their intended outputs'; plus reporting the need for change or innovation; plus ensuring the promotion of customer focus and what was previously in 5.4.2 b) regarding maintaining the integrity of the QMS has been put under this heading instead.



New Clause No and Title

6 Planning for the QMS

Existing Clause No



Summary of Changes

6.1 Actions to address risks and opportunities

6.1.1 The general requirement here is that the QMS must be able to achieve its intended outcomes and refers back to clauses 4.1 & 4.2 as well as the need to determine risks & opportunities.

6.1.2 Having identified the risks and opportunities, there is now a requirement to plan actions to address them and how to integrate them into the QMS and evaluate the effectiveness of these actions. It does point out that the actions should be proportionate.



New Clause No and Title

6 Planning for the QMS

Existing Clause No

5.4.1

Summary of Changes

6.2 Quality objectives and planning to achieve them

6.2.1 This is the existing requirement for quality objectives but has additional requirements for them to be measurable, be relevant to conformity of products and services and customer satisfaction. There are also requirements to monitor, communicate and update the objectives and they must be documented.

6.2.2 A new requirement is for the objectives to be planned with respect to what will be done, what resources will be required, who is responsible, timescales for completion and how results will be evaluated.



New Clause No and Title

6 Planning for the QMS

Existing Clause No

5.4.2

Summary of Changes

6.3 Planning of changes

When the need to change the QMS has been identified, the organisation must consider the purpose and consequences of the change, the risks to the integrity of the QMS, the availability of resources and the allocation of responsibilities and authorities.



New Clause No and Title

7 Support

Existing Clause No

6.1

6.2

6.3

Summary of Changes

7.1 Resources

7.1.1 General

A basic requirement to determine and provide sufficient resources to establish and maintain a QMS. It also calls for consideration of which resources will be provided internally as opposed to those which will be sourced externally.

7.1.2 People

One type of resource identified is people, the requirement is to provide the persons needed to meet requirements and to effectively operate the QMS.

7.1.3 Infrastructure

Virtually unchanged from present 6.3. The examples are now in a note rather than in the main text.



New Clause No and Title

7 Support

Existing Clause No

Summary of Changes

6.4

7.1.4 Environment for the operation of processes

This is also largely unchanged from the current 6.4.

7.6

7.1.5 Monitoring and measuring resources

A slight change in the title (resources rather than equipment) compared to the current 7.6, the requirements of this clause have been changed a reasonable amount but the intent is very much the same as currently.

-

7.1.6 Organisational knowledge

This is a new requirement which calls for the organisation to determine the levels of knowledge needed to control its processes and to achieve conformity of products and services.

6.2

7.2 Competence

This is currently addressed under clause 6.2 and is mostly unchanged – it has been spread out across a number of clause headings.



New Clause No and Title

7 Support

Existing Clause No

6.2

5.5.3

4.2.3 & 4.2.4

Summary of Changes

7.3 Awareness

This was mostly previously addressed under clause 6.2.2 but has added the need for people to be aware of the quality policy and objectives and the implications of not conforming to the QMS.

7.4 Communication

This previously related to internal communication. It has now been expanded and includes internal and external communication along with when, how and with whom to communicate.

7.5 Documented information

7.5.1 General

Whereas the current version of ISO 9001 has 2 clauses relating to the control of documents and records, the proposed changes include changing the title to documented information – which includes both documents and records. This is broken down into information required by the standard and that required by the organisation.



New Clause No and Title

7 Support

Existing Clause No

4.2.3 & 4.2.4

Summary of Changes

7.5.2 Creating and updating

This is a new clause, though the intent to do these actions has always been there but now there is more detail included.

7.5.3 Control of documented information

These requirements are virtually the same as are currently in clauses 4.2.3 & 4.2.4 of ISO 9001:2008, though it is now more clearly stated.



New Clause No and Title

8 Operation

Existing Clause No

Summary of Changes

7.1

8.1 Operational planning and control

This is the equivalent of the current clause 7.1 and the intent is largely unchanged though there are a few small additions and clarifications, plus the requirement to control any outsourced processes is now located here.

7.2

8.2 Determination of requirements for products and services

7.2.3

8.2.1 Customer communication

This is much the same as the current clause but customer property and the need for contingency actions have been added.

7.2.1

8.2.2 Determination of requirements related to products and services

This is almost identical to the current clause 7.2.1 but it has been simplified and the reference to post delivery activities has been removed and put into 8.2.3.



New Clause No and Title

8 Operation

Existing Clause No

7.2.2

7.3

7.4.1

Summary of Changes

8.2.3 Review of requirements related to products and services

Once again, this is almost identical to the existing requirements in clause 7.2.2.

8.3 Design and development of products and services

This is the replacement for the current clause 7.3 and largely requires the same controls but the clause has been simplified.

8.4 Control of externally provided products and services

This requirement includes what is currently included in the purchasing clause (7.4) and it also includes any outsourced processes (currently addressed in clause 4.1).



New Clause No and Title

8 Operation

Existing Clause No

7.4.1

7.4.1 & 7.4.3

7.4.2

Summary of Changes

8.4.1 General

A statement that externally provided processes, products and services must conform to specified requirements. It is down to the organisation to decide the necessary controls. It also includes a very similar requirement to the current version regarding the selection of suppliers (now termed external providers).

8.4.2 Type and extent of control of external provision

There is a statement regarding the type and amount of controls to be applied should be dependant on the risks involved and their potential impacts. There is also the requirement to verify that the externally provided products and services are conforming. Records of these activities are to be maintained.

8.4.3 Information for external providers

This clause is based on what is currently in clause 7.4.2 but there also a few additions and clarifications.



New Clause No and Title

8 Operation

Existing Clause No

7.5.1 & 7.5.2

7.5.3

7.5.4

Summary of Changes

8.5 Production and service provision

8.5.1 Control of production and service provision

This clause is the equivalent of clauses 7.5.1 and 7.5.2 of the current version of ISO 9001. It is not identical but contains very similar information plus a few additions.

8.5.2 Identification and traceability

This is almost identical to the current requirement (currently clause 7.5.3) with a few clarifications.

8.5.3 Property belonging to customers or external providers

This requirement is almost identical to the existing clause on the subject (customer property, currently clause 7.5.4).



New Clause No and Title

8 Operation

Existing Clause No

7.5.5

7.2.1

Summary of Changes

8.5.4 Preservation

Very similar to the existing clause (7.5.5) but with a little more emphasis on process outputs in relation to provision of services rather than products.

8.5.5 Post delivery activities

This is mostly a new requirement, though there was previously mention in clause 7.2 – this clause provides more detail of the requirement.

8.5.6 Control of changes

This is a new clause title but there are links into the existing clauses 4.2.3 (controlling changes to documents) and clause 5.4.2 (controlling changes to the QMS. This clause has brought these 2 elements together under 1 heading.

8.6 Release of products and services

Whilst this is a new title, the requirements are very similar to the existing clause 8.2.4 (monitoring and measurement of product).



New Clause No and Title

8 Operation

Existing Clause No

7.2.1

Summary of Changes

8.7 Control of nonconforming process outputs, products and services

Almost the same as the existing clause 8.3 (control of nonconforming product) but slightly re-worded. The clause also includes some of the options available should non-conformances occur. There is also a requirement to maintain documented information regarding the nature of nonconformities discovered, the actions taken and the person/authority making the decision regarding concessions.



New Clause No and Title

9 Performance evaluation

Existing Clause No

8.2

8.2.1

Summary of Changes

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 The content of this clause is largely what is currently in clause 8.2 monitoring and measurement but it has been further developed.

Overall, this clause has pulled together the monitoring and measuring activities, added to them and requires the organisation to consider what they expect to achieve and how closely they have met those expectations.

9.1.2 Customer satisfaction

This is largely unchanged in its requirements though it has been clarified and re-worded.



New Clause No and Title

9 Performance evaluation

Existing Clause No

8.4

8.2.2

Summary of Changes

9.1.3 Analysis and evaluation

This is very similar to the existing clause 8.4 (though more clearly explained) in requiring the organisation to analyse the data obtained through the monitoring and measuring activities described in previous clauses. The results are to be fed into management reviews.

9.2 Internal audit

Very similar in requirements to the existing clause 8.2.2 but it has been re-worded and additional elements introduced such as the need to take into consideration the quality objective and customer feedback when programming audits.



New Clause No and Title

9 Performance evaluation

Existing Clause No

5.6

5.6.1

5.6.2

5.6.3

Summary of Changes

9.3 Management Review

9.3.1 The basic requirement to conduct management reviews of the QMS is much the same as in the existing clause 5.6 but it now requires the organisation to take into account the business' strategic direction and changing business environment.

What are currently labelled as inputs, are now 'considerations' and whilst similar to the existing inputs, they are more clearly defined and rely heavily on utilising the data generated from monitoring and measuring activities as defined in earlier clauses.

9.3.2 The outputs from management review are largely unchanged.



New Clause No and Title

10 Improvement

Existing Clause No

8.43 & 8.5.2

8.5.1

Summary of Changes

10.1 General

This is a general statement about the need to improve processes, products & services and QMS results.

10.2 Nonconformity and corrective action

These 2 previously separate clauses have now been put together and whilst worded differently, the intentions are the same.

10.3 Continual Improvement

Similar to the existing clause 8.5.1 the sources of information used to drive improvement have changed. It now also requires the identification of any underperformance to be addressed and refers to the use of tools and methodologies to assist in this process.

Annex B – Quality Management Principles

The existing 8 quality management principles upon which ISO 9001 is founded are not currently in ISO 9001, but are in ISO 9000. There are now only 7 principles, they have been re-worded and included as a statement and also the rationale behind the principle. They are:

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence based decision making
7. Relationship management





Terms and definitions

- interested party
- person or organization (3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity
- EXAMPLE Customers (3.26), owners, people in an organization (3.01), suppliers (3.27), bankers, unions, partners or society that may include competitors or opposing pressure groups.
- [SOURCE: ISO DIS 9000:2014, 3.2.4]



Objective

- result to be achieved
- Note 1 to entry: An objective can be strategic, tactical, or operational.
- Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product (3.47), service (3.48), and process (3.12)).
- Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality (3.37) objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).
- Note 4 to entry: In the context of quality management systems (3.33),
- quality objectives are set by the organization (3.01), consistent with the quality policy (3.34), to achieve specific results.



Risk

- effect of uncertainty on an expected result
- Note 1 to entry: An effect is a deviation from the expected — positive or negative
- Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information (3.50) related to, understanding or knowledge (3.53) of, an event, its consequence, or likelihood.
- Note 3 to entry: Risk is often characterized by reference to potential “events” (as defined in ISO Guide 73:2009, 3.5.1.3) and “consequences” (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.
- Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.
- Note 5 to entry: The term “risk” is sometimes used when there is only the possibility of negative consequences



Documented Information

- information (3.50) required to be controlled and maintained by an organization (3.01) and the medium on which it is contained
- Note 1 to entry: Documented information can be in any format and media and from any source.
- Note 2 to entry: Documented information can refer to:
 - - the quality management system (3.33), including related processes (3.12);
 - - information (3.50) created in order for the organization (3.01) to operate (documentation);
 - - evidence of results achieved (records).



Process

- set of interrelated or interacting activities which transforms inputs into outputs (3.46)
- Note 1 to entry: Inputs to a process are generally outputs (3.46) of other processes.
- Note 2 to entry: In some processes, some inputs become outputs (3.46) without any transformation e.g. a blueprint used in a manufacturing process or a catalyst in a chemical process.
- Note 3 to entry: Processes in an organization (3.01) are generally planned and carried out under controlled conditions to add value.
- Note 4 to entry: A process where the conformity (3.18) of the resulting output (3.46) cannot be readily or economically validated is frequently referred to as a “special process”.



Performance

- measurable result
- Note 1 to entry: Performance can relate either to quantitative or qualitative findings.
- Note 2 to entry: Performance can relate to the management (3.29) of activities, processes (3.12), products (3.47), services (3.48), systems (3.31) or organizations (3.01).



Outsource (verb)

- make an arrangement where an external organization (3.01) performs part of an organization's function (3.25) or process (3.12)
- Note 1 to entry: An external organization (3.01) is outside the scope of the management system (3.04), although the outsourced function (3.25), or process (3.12), is within the scope.




Monitoring

- determining (3.67) the status of a system (3.31), a process (3.12) or an activity
- Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.
- Note 2 to entry: Monitoring is generally a determination (3.67) of the object (3.36) being monitored, carried out at different stages or at different times.



Context of the Organization

- business environment combination of internal and external factors and conditions that can have an effect on an organization's (3.01) approach to its products (3.47), services (3.48) and investments and interested parties (3.02)
- Note 1 to entry: The concept of context of the organization is equally applicable to not-for-profit or public service (3.48) organizations (3.01) as it is to those seeking profits.
- Note 2 to entry: In English this concept is often referred to by other phrases such as business environment, organizational environment or ecosystem of an organization (3.01).
- function
- role to be carried out by a designated unit of the organization (3.01)
- improvement

- 
- activity to enhance performance (3.13)
 - Note to entry: Improvement can be achieved by a recurring o
by a singular activity.
 - infrastructure
 - system (3.31) of facilities, equipment and services (3.48)
needed for the operation of an organization
 - strategy
 - planned activities to achieve an objective (3.08).



Innovation

- process (3.12) resulting in a new or substantially changed object (3.36)
- Note 1 to entry: The object (3.36) for the purpose of innovation can be e.g. a management system (3.04), a process (3.12), a product (3.47), a service (3.48) or technology.



Quality Objective

- objective (3.08) related to quality (3.37)
- Note 1 to entry: Quality objectives are generally based on the organization's (3.01) quality policy (3.34).
- Note 2 to entry: Quality objectives are generally specified for relevant functions (3.25) and levels in the organization (3.01).



Output

- result of a process (312)
- Note 1 to entry “output”: There are four generic output categories, as follows:
 - — services (e.g. transport);
 - — software (e.g. computer program, dictionary);
 - — hardware (e.g. engine 746 mechanical part);
 - — processed materials (e.g. lubricant)
- Note 2 to entry “output”: The ownership of a product can usually be transferred. This is not necessarily the case for a service.



Performance Indicator

- performance metric
- characteristic (3.65) having significant impact on realization of the output (3.46) and customer satisfaction (3.57)
- EXAMPLES Nonconformities (3.19) per million opportunities, first time capability, nonconformities per unit.
- Note to entry: The characteristic (3.65) can be quantitative or qualitative



More on outputs

- Many outputs comprise elements belonging to different generic output categories. Whether the output is then called service, product, software, hardware or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).



Some News

- information
 - meaningful data (3.49)
- information system
 - network of communication channels used within an organization (3.01)
- knowledge
 - available collection of information (3.50) being a justified belief and having a high certainty to be true
- data
 - facts about an object (3.36)
- feedback
- opinions, comments and expressions of interest in a product, a service or a complaints-handling process
- release
- permission to proceed to the next stage of a process (3.12)
- Note to entry: In English, in the context of software and documented information (3.11), the word “release” is frequently used to refer to a version of the software or the documented information itself.



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