IRCA CERTIFIED TRAINING COURSE

IQCS Certification

IRCA (UK) Approved Auditor Training Organisation

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

Contents

New Clause No and Title

1 Scope

Existing Clause No	Summary of Changes
1	‘Product’ becomes ‘product or service’ Note 1 b) Has been removed 1.2 Application, removed

2 Normative References

Existing Clause No	Summary of Changes
2	There are no normative references – clause has been included to maintain numbering alignment

New Clause No and Title

3 Terms & Definitions

Existing Clause No	Summary of Changes
3	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	Summary of Changes
4	**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	Summary of Changes
4.1	**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	Summary of Changes
5.2	**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.
5.3	**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	Summary of Changes
5.5	**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	Summary of Changes
5.4.1	**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	Summary of Changes
5.4.2	**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	Summary of Changes
6.1	**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.
6.2	**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.
6.3	**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	Summary of Changes
4.2.3 & 4.2.4	**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	Summary of Changes
7.2.2	**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.
7.3	**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.
7.4.1	**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	Summary of Changes
7.4.1	**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).
7.4.1 & 7.4.3	**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.
7.4.2	**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	Summary of Changes
7.5.1 & 7.5.2 7.5.3 7.5.4	**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	Summary of Changes
7.5.5	**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.
7.2.1	**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	Summary of Changes
7.2.1	**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	Summary of Changes
8.2	**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.
8.2.1	**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	Summary of Changes
8.4	**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.
8.2.2	**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	Summary of Changes
5.6 5.6.1 5.6.2 5.6.3	**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 form 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 73:209, 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.

AUDITING THE ISO 9001:2015 REQUIREMENTS

1.1 The Creation of ISO 9000 Series as Harmonized Standards

- International Organization for Standardization's technical committee, ISO/TC 176 was formed in 1979.
- Before that, there were various national and multinational quality systems standards.

1.2 The Background and Origins of ISO 9000

- ISO (1946) is a non-governmental organization based in Geneva, Switzerland
- Promotes the development of international standards and related activities to facilitate the exchange of products and services globally.

1.2.1 ISO/TC 176

ISO/TC 176 is in charge of finalizing QA requirements in a wide international consensus.

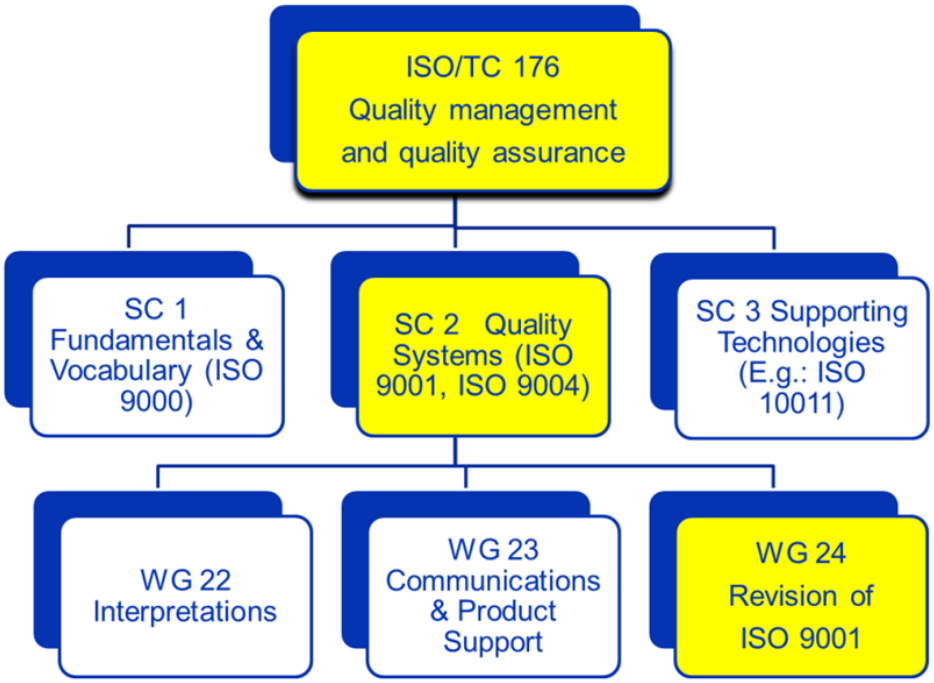


Table 1: ISO Committee

QA Standards- The Milestones

1963	**Mil-Q-9858A**	**US Military**
1969	**AQAP**	**NATO**
1970	**10CFR50**	**US Federal Regulation**
1971	**ANSI-N45-2**	**American Standard**
1973	**Defence Standard 05-21**	**UK version of AQAP**
1975	**CSAZ299**	**Canadian Standard**
1979	**BS 5750**	**British Standard**
1979	**ANSI-A.S.Q.C.Z1.15**	**Generic Standard**
1985	**CSAZ299 (Revision)**	
1987	**ISO 9000 Series - Quality Assurance**	
1994	**ISO 9000 Series 1st phase changes**	
	ISO 9000 Series 2nd phase changes – Quality management	
2005	**ISO 9000 Revision**	
	ISO 9001 Revision – Process approach	
	ISO 9004 Revision	
2015	**ISO 9001:2015 - High level structure (Annex SL)**	

1.3 Continuing Development of ISO 9000 Standards

- All standards reviewed approximately every five years.
- The purpose of this review is to ensure that it is usable and remain applicable to all organizations regardless of their size, industry or product.

Stages in development process

- Working Drafts (WDs)
- Committee Draft (CD)
- Draft International Standard (DIS)
- Final Draft International Standard (FDIS)
- International Standard (IS)

1.3.1 Reasons For The Changes

- In the last 25 years, many other Management Systems Standards have come into use world wide.
- Organizations that use multiple Management System Standards are increasingly demanding a common format and language that is aligned between those standards.

Standard	number of certificates in 2014	number of certificates in 2013	evolution	evolution in %
ISO 9001	1 138 155	1 126 460	11 695	1 %
ISO 14001	324 148	301 622	22 526	7 %
ISO 50001	6 778	4 826	1 952	40 %
ISO/IEC 27001	23 972	22 349	1 623	7 %
ISO 22000	30 500	26 847	3 653	14 %
ISO/TS 16949	57 950	53 723	4 227	8 %
ISO 13485	27 791	25 655	2 136	8 %
ISO 22301	1 757			
TOTAL	**1 609 294**	**1 561 482**	**47 812**	**3 %**

Table 2: ISO CASCO Report 2014

1.4 Key Perspectives and Tasks

- ISO 9001 needs to:
- Maintain relevance
- Integrate with other management systems
- Provide an integrated approach to organizational management
- Provide a consistent foundation for the next 10 years
- Reflect the increasingly complex environments in which organizations operate
- Ensure the new standard reflects the needs of all potential user groups
- Enhance an organization's ability to satisfy its customers

1.4.1 The main changes in the new version of ISO 9001:2015 are:

- The adoption of the HLS as set out in Annex SL of ISO Directives Part 1.
- An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
- Fewer prescribed requirements.
- Less emphasis on documents.
- Improved applicability for services.
- A requirement to define the boundaries of the QMS.
- Increased emphasis on organizational context.
- Increased leadership requirements.
- Greater emphasis on achieving desired outcomes to improve customer satisfaction

1.5 Structure of ISO 9000 Series

•The Process-Based structure is consistent with the Plan-Do-Check-Act improvement cycle.

•Consistent with other ISO management system standards

•The quality management principles have been identified to assist the achievement of quality.

1.6 ISO 9000 Core Standards

Standard	Title
ISO 9000	Quality Management Systems – Fundamentals and Vocabulary
ISO 9001	Quality Management Systems – Requirements
ISO 9004	Managing for the sustained success of an organization — A quality management approach

Figure 1.2: ISO 9000 Series of Standards

The 9000 series consists of 3 standards, namely ISO 9000, ISO 9001 and ISO 9004.

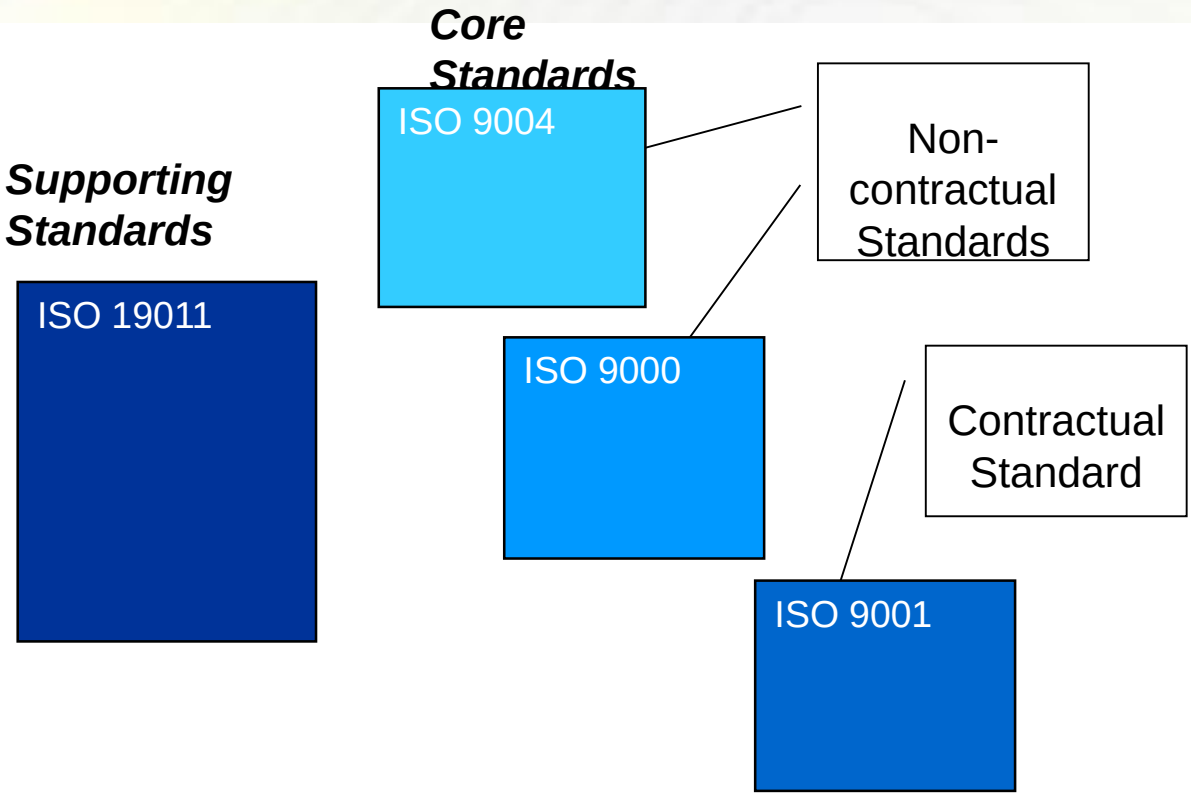


Figure 1.3: Family of ISO 9000 Standards

- The family consists of conformance standards, reference standards, guidelines standards and supporting standards.
- ISO 9001 is the sole auditable or conformance standard.
- Auditable or conformance standard-> “contains only those requirements that may be objectively audited for certification/registration purposes and/or self declaration purposes".

1.7 ISO 9000 Supporting Standards

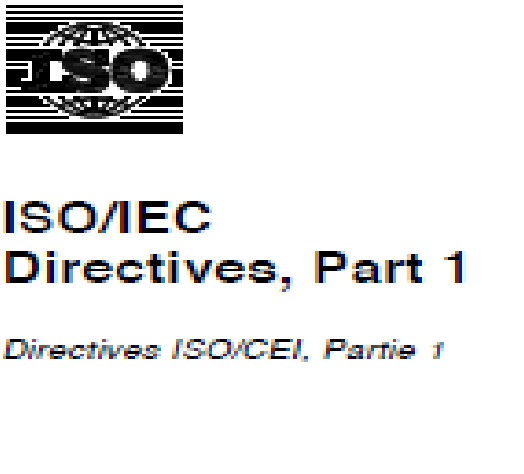
1.7.1 ISO 19011:2011

Guidelines for auditing management systems

Replaces ISO 19011 : 2002 Guidelines on Quality and Environmental Auditing.

1.8 ISO Directives 1 and 2

“ The biggest event from ISO 9001:2015”



- The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC directives, part 1.
- In particular the different approval criteria needed for the different types of ISO documents should be noted.
- This document was drafted in accordance with the editorial rules of the ISO/IEC directives, part 2 (see www.iso.org/directives).

1.8.1 High Level Structure – Common Text Annex SL

- Mandated by ISO's Technical Management Board (TMB).
- High level structure, identical core text and common terms and core definitions for use in all Management System Standards.
- Purpose - Enhance the consistency and alignment of different management system standards.
- Organizations who implement a single system addressing multiple standards (e.g. QMS, EMS, ISMS etc) will see the most potential benefit.

High Level Structure

a new common format has been developed for use in all management system standards
standardized core text and structure
standardized core definitions

Annex SL - What is it?
It is an annex within ISO/IEC Directive Part 1, 6th Edition, that addresses the common structure of a management system.

Organizations implementing multiple management systems (e.g. quality, environmental, information security) can achieve better integration and easier implementation

The high level structure and common text is public information and can be found in Annex SL of the www.iso.org/directives

1.9 ISO 9000 Certification / Registration

1.9.1 Reasons for Certification / Registration

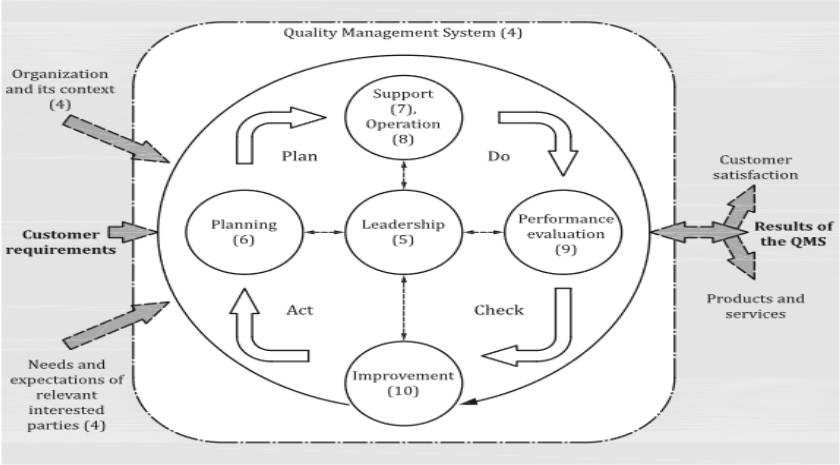
- Certification by any accredited registrars can replace second party audits by customers.
- Beneficial to customers whose suppliers are located overseas.
- To enhance the company's quality image
- To ensure continual improvement

1.9.2 Benefits of Certification / Registration

- To satisfy customer contractual requirements
- To reduce the number of second party audits
- To gain a competitive advantage by improving the quality of products and services through ISO 9001.
- To improve communications between all levels of personnel\

1.10 ISO 9001:2015 QMS Requirements

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Fig. 1.4 Process Approach Model of QMS

KEY AUDIT REQUIREMENTS OF ISO 9001:2015 STANDARD

CLAUSE 1 SCOPE
Applicability – Exclusions

▪This International Standard does not refer to “exclusions” in relation to the applicability of its requirements to the organization’s quality management system.

▪However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization’s activities and the nature of the risks and opportunities it encounters.

Applicability – Exclusions

▪The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system.

▪The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

CLAUSE 4 CONTEXT OF THE ORGANIZATION

One interesting sample from IRCA?

Organisational context

Purpose: Clothing manufacturer

Intended outcome: Production of men's 3 piece suits

Internal issues
- Automation
- Workforce
- Design secrets
- Capacity
- Company culture
- Innovation

External issues
- Customers
- Fashion
- New markets
- Deadlines
- Competition
- Regulators
- Utilities

(Relevant) interested parties
- Consumers
- Employees
- Owners/shareholders
- Society
- Suppliers and partners

CLAUSE 5 LEADERSHIP

5.1 Leadership and commitment

- Auditors must seek evidence that top management has a “hands-on” approach to the management of their quality management system.
- Auditors must understand which ISO 9001:2015 requirements top management can delegate and which they cannot.

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CLAUSE 6 PLANNING

The main objectives of ISO 9001:

- Give assurance that the QMS can achieve its intended result(s)
- Enhance desirable effects
- Prevent, or reduce, undesirable effects
- Achieve improvement

DON'T FORGET

The goal of RISK MANAGEMENT is to protect organizations from being vulnerable

What is “risk-based thinking”?

- Risk-based thinking is something we all do automatically and often sub-consciously
- The concept of risk has always been implicit in ISO 9001 – this revision makes it more explicit and builds it into the whole management system
- Risk-based thinking is already part of the process approach
- Risk-based thinking makes preventive action part of the routine
- Risk is often thought of only in the negative sense. Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk

The RISK – new requirements

- Identification and management of risk is being viewed as a new system wide strategy in much the same light that Continual Improvement was when ISO 9001:2000 was published.
- Borrows heavily from the concept of Preventive Action (clause 8.5.3 in ISO 9001:2008.)
- Preventive Action isn’t going anywhere! (the standard itself)
- Expands the idea of Risk aversion to one that affects all of the various areas of the Quality Management System.

Risk in the clauses - Process Approach, Leadership, Planning

- Clause 4 - the organization is required to determine the risks which can affect its ability to meet these objectives
- Clause 5 - top management are required to commit to ensuring Clause 4 is followed
- Clause 6 - the organization is required to take action to address risks and opportunities

Risk in Clauses – Operation, Evaluation, Improvement

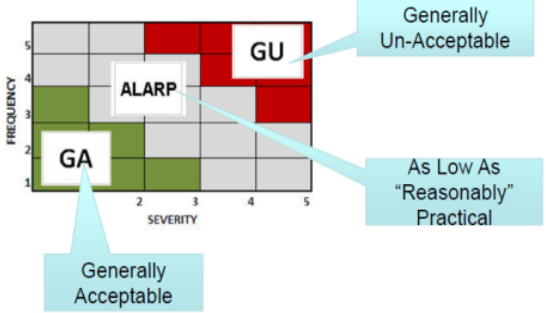
- Clause 8 - the organization is required to have processes which identify and address risk in its operations
- Clause 9 - the organization is required to monitor, measure, analyse and evaluate the risks and opportunities
- Clause 10 - the organization is required to improve by responding to changes in risk

Risk Based thinking

Intuition isn't always enough.

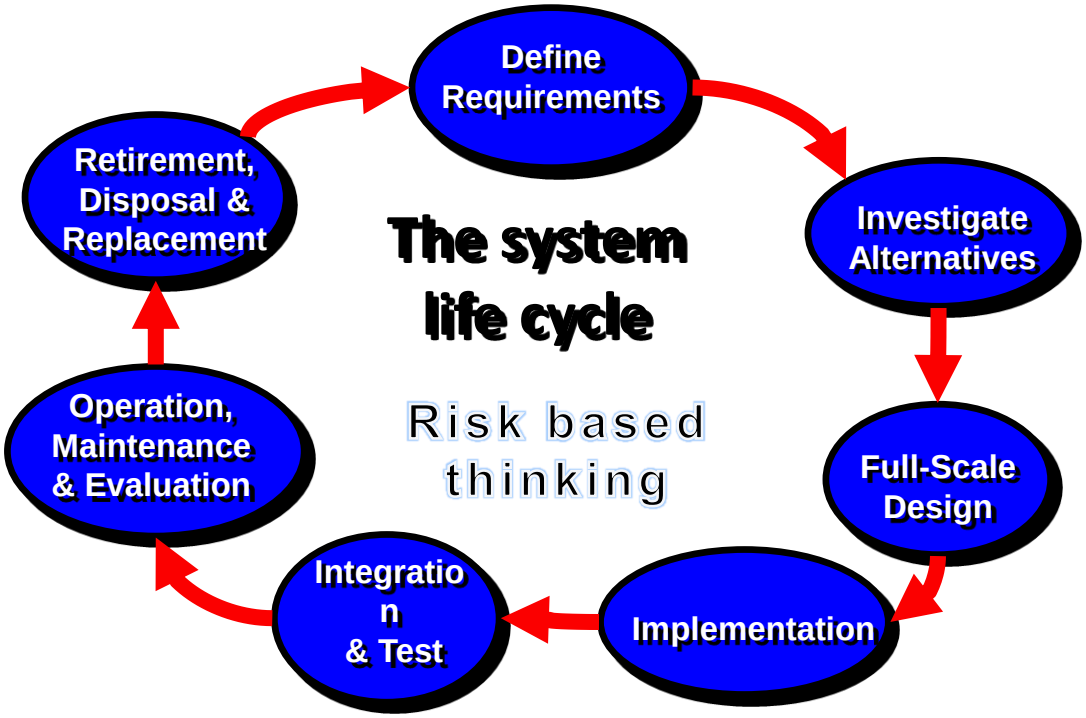
Use of risk based thinking

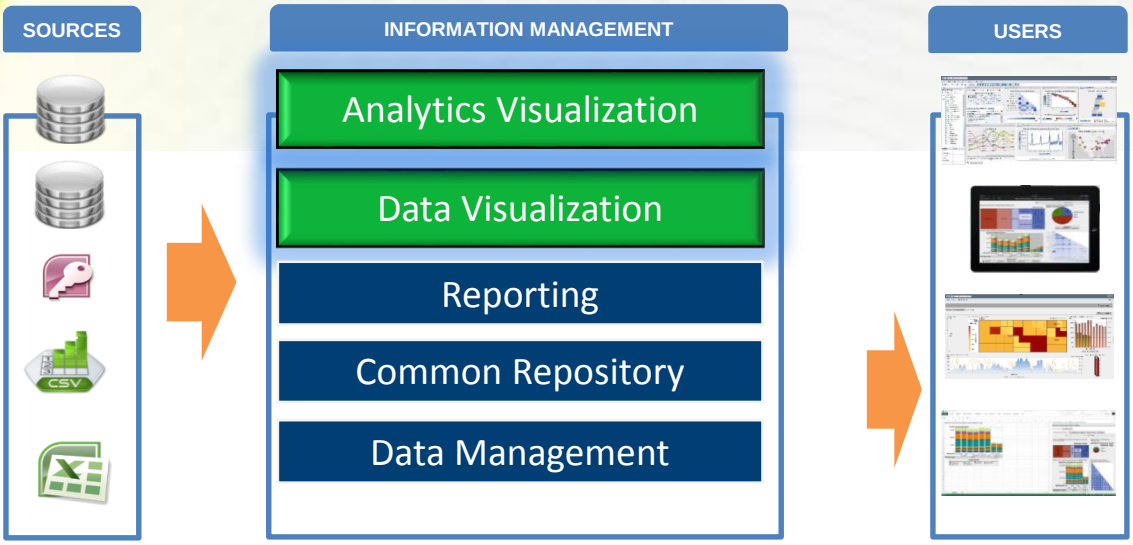
- By considering risk based thinking throughout the organization the likelihood of achieving stated objectives is improved, output is more consistent and customers can be confident that they will receive the expected product or service.
- Risk-based thinking therefore:
  - builds a strong knowledge base
  - establishes a proactive culture of improvement
  - assures consistency of quality of goods or services
  - improves customer confidence and satisfaction



Auditor's answer on Risk Based Thinking

- A way of understanding reality that emphasizes the relationships among a system's parts, rather than the parts themselves and their relationship to a functioning whole
- Systems Thinking is the only good answer and concept auditor need to implement during preparation and audit executions
- What are alternatives – pushing audit clients to used RM methodologies auditor likes or familiar (SWOT, Delphi Technique, Preliminary Hazard Analysis (PHA), HAZOP , Business impact Failure Modes and Effects Analysis (FMEA) and Failure Modes and Effects and Criticality analysis (FMECA) , Fault Tree Analysis (FTA) or others).





With the ISO 9001:2015 "Risk-Based Management System" requirement, a traditional data management & reporting system is no longer sufficient…companies require a more advanced system to manage their risks & opportunities

Source – SAS' Visual Analytics

To manage an effective Risk-Based-Thinking System, companies are required to analyse all their business related data so as to visualise their future market risks & opportunities…

Source – SAS' Visual Analytics

Risk based thinking or Risk management addresses

Auditors don't forget or neglect

- System risk
- Project risk
- Business risk
- Safety, environmental and risks to the public

Auditors don't forget or neglect

- Good risk management or Risk based thinking will not prevent bad things from happening.
- But when bad things happen, good risk management or risk based thinking will have anticipated them and will reduce their negative effects.

CLAUSE 7 SUPPORT

CLAUSE 7.1.6 ORGANIZATIONAL KNOWLEDGE

- The Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services.
- Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g.

- ❖ through staff turnover;
- ❖ failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g.

- ❖ learning from experience;
- ❖ mentoring;
- ❖ benchmarking.

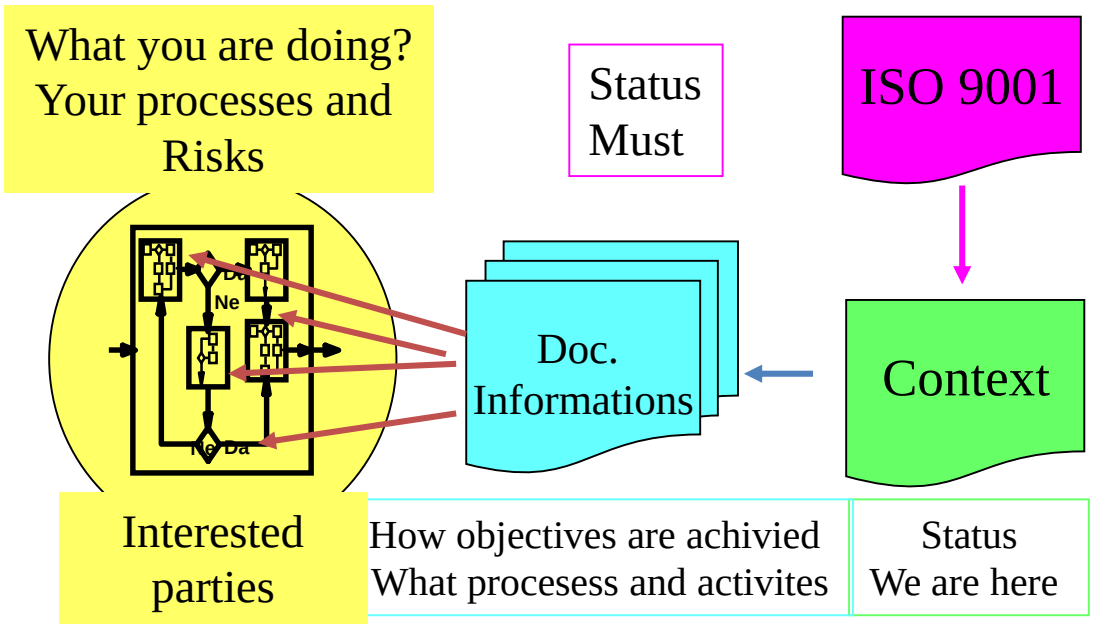
- Auditors should ensure that organisations have taken steps to identify the organisational knowledge necessary to establish the continuing conformity of their products and services.
- Auditors should ensure that organisational knowledge has been communicated as necessary within the organisation and that it is being maintained and protected.
- They should also ensure that an assessment of organisational knowledge has taken place prior to any changes made to the quality management system in response to changing needs or trends.

CLAUSE 7.5 DOCUMENTED INFORMATION

7.5.3 Control of documented information

- Auditors will increasingly find themselves having to access and use electronic systems in order to evidence how organisations are controlling their documented information. This could require a technical upskilling.

QMS Documented Informations



CLAUSE 8 OPERATION

8.1 Operational planning and control

- This section should be implemented in conjunction with clause 4.4. The increased focus on the process approach makes properly understanding clause 4.4 and clause 8.1 a fundamental requirement for auditors.

- Besides the change in the title (“production and service provision”), auditors should note that this clause now includes implementation and control requirements, not just planning and development requirements as per ISO 9001:2008.

- It is very clear (clause 4.4, supported with clause 8.1), that the organization is required to determine and plan (design) its processes to meet requirements.

- As such, auditors need to evidence that this has been done, ie evidence that the process (including process inputs, outputs, resources, controls, criteria, process measurement and performance indicators) has been planned.

- There is also a clear link and, hence, audit trail, from clause 6.1 “Actions to address risks and opportunities” through to clause 8.1.

- For those risks and opportunities that the organisation has determined need to be addressed, auditors should gather evidence that these actions have been integrated into the management system;

- Auditors also need to seek evidence that processes have been implemented and controlled as planned, and in so far as they relate to process planning and control, evidence that the organisation has evaluated the effectiveness of actions taken to address risks and opportunities.

- Auditors should also gather and evaluate evidence relating to planned changes and to any unintended changes.

8.4 Control of externally provided processes, products and services

- All forms of externally provided processes, products and services are addressed in 8.4, e.g. whether through:
  - purchasing from a supplier;
  - an arrangement with an associate company;
  - outsourcing processes to an external provider.

- Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

- Auditors should note the new requirement for the organization to establish criteria to allow it additionally to monitor the performance of external providers. This must be maintained as documented information.

- They should also note the requirement for organisations to provide a record of the results of their monitoring of the external provider's performance as documented information.

8.4.2 Type and extent of control of external provision

- Auditors should note the revised requirements as set out above, including those relating to outsourced processes

8.5.5 Post-delivery activities

- Auditors should be aware that these are new requirements.
- They should ensure that the organisation has taken into account the necessary considerations when determining the nature and extent of post-delivery activities.

8.5.6 Control of changes

- Auditors should evidence that the organisation has controlled unplanned changes in accordance with the requirements set out above.

- Auditors should evidence that organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

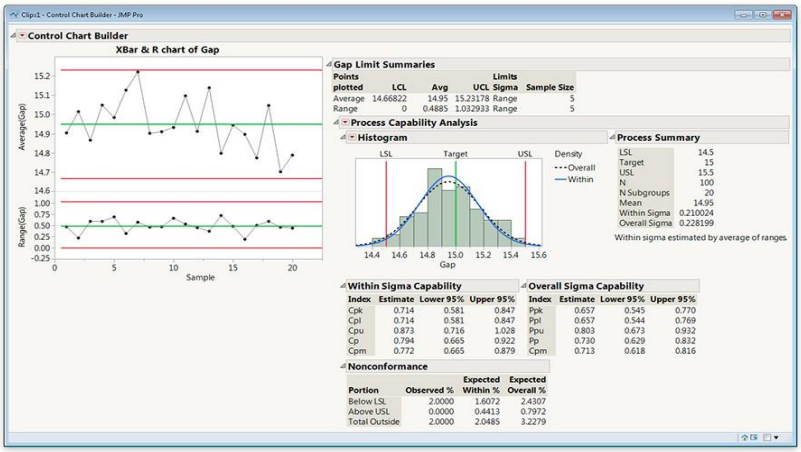
CLAUSE 9 PERFORMANCE EVALUATION

Monitoring, Measurement, Analysis and Evaluation

- The organization shall determine:
  a) what needs to be monitored and measured;
  b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
  c) when the monitoring and measuring shall be performed;
  d) when the results from monitoring and measurement shall be analysed and evaluated.

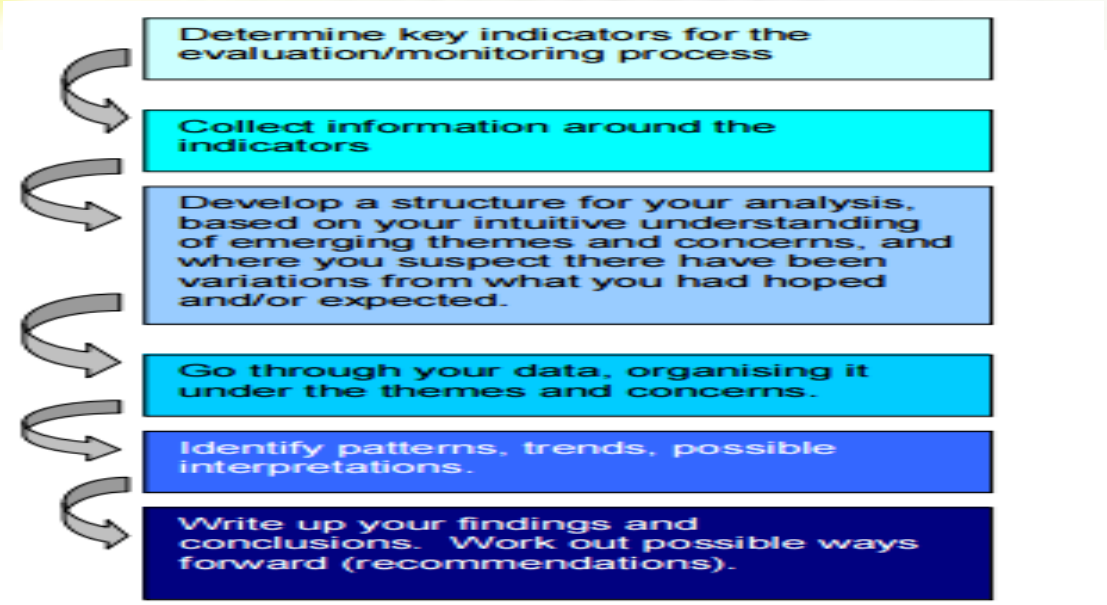
- The organization shall evaluate the performance and the effectiveness of the quality management system.

Monitoring, Measurement, Analysis and Evaluation Mechanisms



The market demands continual improvement, the software based solution in monitoring, measuring, analyzing & evaluating company's process & product performance accelerate time to market, protect company brand by minimizing customer complaints

Monitoring – crucial for auditing



Monitoring involves:

- Establishing indicators of efficiency, effectiveness and impact;
- Setting up systems to collect information relating to these indicators;
- Collecting and recording the information;
- Analysing the information;
- Using the information to inform day-to-day management.

Evaluation involves:

- Looking at what the project or organisation intended to achieve – what difference did it want to make? What impact did it want to make?
- Assessing its progress towards what it wanted to achieve, its impact targets.
- Looking at the strategy of the project or organisation. Did it have a strategy? Was effective in following its strategy? Did the strategy work? If not, why not?
- Looking at how it works
- Was there an efficient use of resources?
- What were the opportunity costs of the way it chose to work?
- How sustainable is the way in which the project or organisation works?
- What are the implications for the various stakeholders in the way the organisation works.

Specific interest of auditors connected with 8.4 but also with 4.1, 4.2, 4.3, 6.1 and 6.2 clauses of ISO 9001:2015

- Control of externally provided processes, products and services

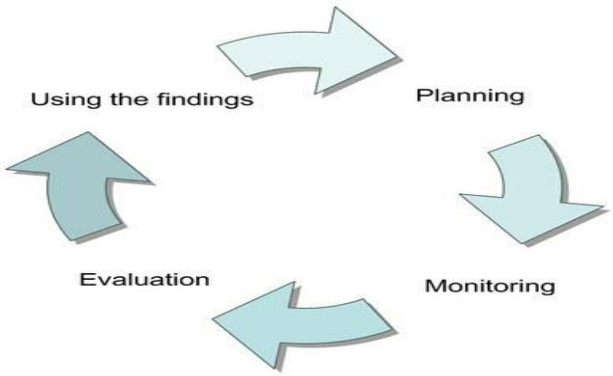
Auditor need to consider following areas of monitoring and evaluations during audit

- Relevance: Do the objectives and goals match the problems or needs that are being addressed?
- Efficiency: Is the project, program, changes or any activities delivered in a timely and cost-effective manner?
- Effectiveness: To what extent does the intervention achieve its objectives? What are the supportive factors and obstacles encountered during the implementation?
- Impact: What happened as a result of the activities? This may include intended and unintended positive and negative effects.
- Sustainability: Are there lasting benefits after the intervention is completed?

Monitoring and evaluation results - Validation and verification aspect

- Validation:
  building the right system
- Verification:
  building the system right

- Auditors need to understand clearly



- This loop need to be closed

Auditor needs to understand differences

[Source: Zall Kusek J, Rist R. Ten steps to a results-based monitoring and evaluation system. A handbook for development practitioners. Washington D.C.: The World Bank, 2004: p.14

Monitoring	Evaluation
Clarifies program objectives	Analyzes why intended results were or were not achieved
Links activities and their resources to objectives	Assesses specific casual contributions of activities to results
Transelates objectives into performance indicators and set target	Explores implementation process
Routinely collects data on these indicators, compares actual results with targets	Explores unintended results
Reports progress to managers, policy-makers and/or donors and alerts them to problems	Highlights accomplishments or program potential; provides lessons learned; offers recommendations for improvement

Management Review: A Process, Not an Event

- Management review is often misunderstood and underutilized, but it is the process that supports continuous improvement and emphasizes its importance in the drive for success.
- Successful organizations use frequent management reviews to foster continuous improvement.
- Continuously reviewing (and achieving) management goals can ensure an organization's success.
- Not by accident, management review is an essential requirement of the ISO 9001 standard.

Management Input/Feedback/Decisions

- Are we headed in the right direction?
- Are changes needed? Can we get better?
- How do we change and do you agree with the plan?
- Do we have your ongoing commitment?
- Are you willing to provide the resources?

Auditor KEY interests :

CLAUSE 10 IMPROVEMENT

- Nonconformity and Corrective Action
- Continual Improvement