TRANSNET

Academy

Faculty of Leadership and Functional Development

Course Title: ISO 9001:2015 Introduction

Learner Guide

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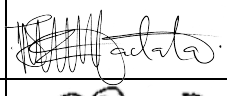
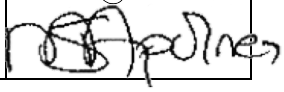
Original	Lawrence Madala	17/04/2023	
Reviewer	Motshabi Moloatse	07.04.2023	

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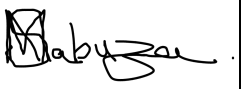
Corporate Safety Office- TCC	Programme Manager: Interim Review, Benefit Realisation & Post Implementation Review	N. Mabuza	11/04/2023	
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CONTENTS

PURPOSE OF THE UNIT COURSE

This course has been carefully designed to allow delegates to understand the benefits of adopting a Quality Management System (QMS) and achieving certification to the International Quality Standard ISO 9001:2015. The clauses of ISO 9001:2015 are reviewed in conjunction with the requirements of ISO 9004:2009 allowing for a greater understanding of the requirements of this international standard.

LEARNING ASSUMED TO BE IN PLACE AND RECOGNITION OF PRIOR LEARNING

It is assumed that a learner will be competent in:

1. Communication at ABET Level 3 or equivalent.
2. Mathematical Literacy at ABET Level 3 or equivalent.

UNIT STANDARD RANGE

N/A

FACILITATOR'S ROLES AND RESPONSIBILITIES

The Facilitator is expected to (but not limited to):

1. Encourage collaboration and self-learning
2. Building a safe, structured environment that promotes communication, collaboration and creativity amongst the group
3. Stimulate discussions, ask questions to get the group thinking, and encourage peer-to-peer communication
4. Where necessary, assist with practical demonstrations

LEARNER'S ROLES AND RESPONSIBILITIES

The learner is expected to:

1. Bring their ID Documents
2. Sign the Attendance Register
3. Complete the Learner Registration Form
4. Complete the Programme Evaluation Form
5. Complete and submit all assessments
6. participating professionally where interaction is required
7. being punctual when breaks are allowed
8. avoiding all outside distractions – working on laptops or phones during training is not allowed leaving the classroom silently if there is a need to attend to an external situation, which they are welcome to do

9. asking questions when in doubt

LEARNING OUTCOMES

The qualifying learner will be able to demonstrate an understanding of:

1. The background of ISO standards
2. The history of ISO standards
3. Annex SL
4. The process approach
5. Risk-based thinking
6. ISO 9001 development timeline
7. ISO 9001 implementation timeline
8. The need for change
9. The Deming Cycle
10. Summary of key changes to ISO 9001:2015
11. Elements of ISO 9001:2015
12. Terms and definitions of ISO 9001:2015
13. Annexure B – Other international standards on quality management and quality
14. management developed by ISO/TC 176
15. Benefits of ISO 9001:2015
16. What quality is
17. Quality management principles
18. ISO 9001:2015

NOTES TO THE LEARNER

1. You are responsible for your own learning – make sure you manage your study, practical, workplace and portfolio time responsibly.
2. Learning activities are learner driven – make sure you use the Learner Guide and Portfolio Guide in the manner intended and are familiar with the Portfolio requirements.
3. The Facilitator is there to reasonably assist you during contact, practical and workplace time of this programme – make sure that you have his/her contact details.

COURSE PREREQUISITES

N/A

ASSESSMENT METHODS

Learners will be assessed in any of the following ways of assessment:	**1. Formative Assessment** In each Learner Guide, several activities are spaced within the content to assist you in understanding the material through application. Please make sure that you complete ALL activities in the Learner Guide, whether it was done during the contact session, or not! **2. Summative Assessment** You will be required to complete a Portfolio of Evidence for summative assessment purposes. A portfolio is a collection of different types of evidence relating to the work being assessed. It can include a variety of work samples.

TARGET AUDIENCE

People who are involved in Quality Management

ICONS USED IN THIS LEARNING UNIT

Icons representing various kinds of information can be found throughout this learning unit. They serve as a "quick-look" reminder of their associated text

ICON	MEANING OF ICON
	**NOTE** This icon indicates important additional information
I 	**GLOSSARY/** **Abbreviation** This icon indicates an alphabetical list of terms/words with explanations.

1 SECTION 1: ISO STANDARDS

1.1 BACKGROUND OF ISO STANDARDS

"ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing international standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee.
International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electro technical standardization."

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

"This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised, through the adoption of a revised clause sequence and the adaptation of the revised quality management principles and of new concepts. It also cancels and replaces the Technical Corrigendum ISO 9001:2015/Cor.1:2009."[1]

History of The ISO 9001 Standard

"In 1971, the British Standards Institute (BSI) published the first UK standard for quality assurance (BS 9000), which was developed for the electronics industry. Then, in 1974, the BSI published BS 5179: Guidelines for Quality Assurance. This led to a shift in the burden of inspection from the customer to the supplier, as quality assurance could be guaranteed by the supplier to the customer through third-party inspection.

Through the 1970s, the BSI organised meetings with industry to set a common standard, which culminated in the BS 5750 standard in 1979. Key industry bodies agreed to drop their own standards and use BS 5750 instead. The purpose of BS 5750 was to provide a common contractual document, demonstrating that industrial production was controlled.

The ISO 9000 certification standard has evolved over several revisions. The initial 1987 version (ISO 9000:1987) had the same structure as the UK Standard BS 5750, with three "'models' for quality management systems, the selection of which was based on the scope of activities of the organisation. The language of this first version of the Standard was influenced by existing US and other Defence Military Standards, so it was more accessible to manufacturing and was well suited to the demands of a rigorous, stable, factory-floor manufacturing process. With its structure of 20 'elements' or requirements, the emphasis tended to be overly placed on conformity with procedures, rather than the overall process of management, which was the original intent.

The 1994 version (ISO 9000:1994) was an attempt to break from the practices which had somewhat clouded the use of the 1987 standard. It also emphasised quality assurance via preventive actions and continued to require evidence of compliance with documented procedures. Unfortunately, as with the first edition, companies tended to implement its requirements by creating shelf-loads of procedure manuals and become burdened with ISO bureaucracy. Adapting and improving processes could be particularly difficult in such an environment.

The 2000 version of the standard (ISO 9001:2000) sought to make a radical change in thinking. It placed the concept of process management at the heart of the standard, making it clear that the essential goals of the standard - which had always been about 'a documented system' not a 'system of documents' - were

reinforced. The goal was always to have management system effectiveness via process performance measures.

The fourth edition of the standard (**ISO 9001:2008**) arrived on 14 November 2008. This revision contains minor amendments only. The aim of this revision is to clarify existing requirements and to improve consistency of approach with other management standards, like ISO 9001:2015.

During September 2015, a revised version – **ISO 9001:2015** – was launched to bring the standard up to date, reflecting latest quality management good practice. While some requirements have been tightened, the standard is now far less prescriptive and has even greater integration with other ISO management standard thanks to a common high-level structure."[2]

1.2 ANNEX SL – THE STRUCTURE OF ALL ISO STANDARDS

What is Annex SL?

It is the new format for all future ISO management system standards.

Note that more information on the Annex SL is available on the referenced documents at the end of this guide.

Where Does It Come from?

ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – "Procedures Specific to ISO. This directive defines the basic procedures to be followed in the development of International Standards and other publications."[3] Within this directive, there is an Annexure, known as Annex SL (normative) – Proposals for Management System Standards.

Appendix 2 in Annex SL contains the high-level structure, identical core text, common terms and core definitions for all management system standards.

The Purpose of Annex SL

- "To ensure standards can be easily integrated across an organisation.
- There are now many standards that organisations may wish to use or be certified to.
- Annex SL allows easy integration for organisations that wish to apply more than one standard within their business activities."

- The structure applies to all management system standards – full ISO standards, technical specifications (TS) and publicly available specifications (PAS)

Annex SL Structure

- Clause 1 – Scope
- Clause 2 – Normative references
- Clause 3 – Terms and definitions
- Clause 4 – Context of the organisation
- Clause 5 – Leadership
- Clause 6 – Planning
- Clause 7 – Support

- Clause 8 – Operation
- Clause 9 – Performance evaluation
- Clause 10 – Improvement

The Process Approach

"A process is defined as a "set of interrelated or interacting activities, which transforms inputs into outputs". These activities require allocation of resources such as people and materials. Inputs and intended outputs may be tangible (such as equipment, materials or components) or intangible (such as energy or information)."

1.3 CLAUSE 0.3.1 PROCESS APPROACH – GENERAL

"This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organisation's effectiveness and efficiency in achieving its intended results. This approach enables the organisation to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organisation can be enhanced.

The process approach involves the systematic definition and management of processes and their interactions, to achieve the intended results in accordance with the quality policy and strategic direction of the organisation. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements

b) the consideration of processes in terms of added value

c) the achievement of effective process performance

d) improvement of processes based on evaluation of data and information

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring of checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks."

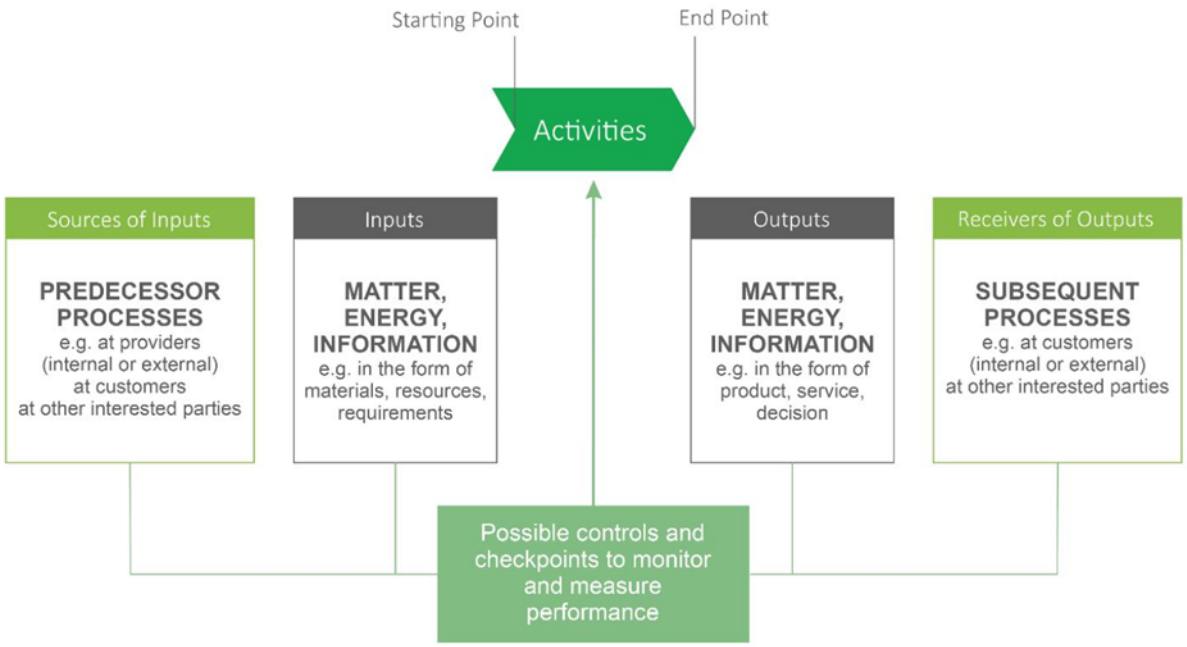


Figure 1: Elements of a single process7

1.4 RISK-BASED THINKING

1.4.1 ANNEX A.4 RISK-BASED THINKING

"The concept of risk-based thinking has been implicit in previous editions of this International Standard, for example, through requirements for planning, review and improvement. This International Standard specifies requirements for the organisation to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed using risk-based thinking to formulate quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organisational responsibilities.

Although 6.1 specifies that the organisation should plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk-management process.

Organisations can decide whether to develop a more extensive risk-management methodology than is required by this International Standard, for example, through the application of other guidance or standards.

Not all the processes of a quality management system represent the same level of risk in terms of the organisation's ability to meet its objectives, and the effects of uncertainty are not the same for all organisations. Under the requirements of 6.1, the organisation is responsible for its application of risk- based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks."

1.4.2 WHY IMPLEMENT RISK-BASED THINKING?

"Risk-based thinking is something we all do automatically and often subconsciously. Risk-based thinking is already part of the process approach"[9], ensuring that everybody consistently thinks about how risks can be prevented. This often results in identifying opportunities for improvement of product and service delivery.

What Is Risk in The Context of Quality Management?

"Risk is the possibility of events or activities impeding the achievement of an organisation's strategic and operational objectives."

The following table provides examples of quality risks

RISK	POSSIBLE LOSS	MITIGATION METHOD
Low customer turnover	Loss of sales and profits	Multifaceted marketing plan
High employee turnover	Customer dissatisfaction	Employee satisfaction committee
Accident – customer injury	Profits, goodwill	Safe practices, insurance
Natural hazards – floods	Facilities	Insurance, planning, secondary facility

1.5 WHAT IS ISO 9004:2009?

"ISO 9004:2009 - Managing for the sustained success of an organization. A quality management approach is a standard that forms part of the ISO 9000 series of documents including ISO9000:2015 Quality management systems - Fundamentals and vocabulary.

ISO 9004:2009 provides guidance to organizations to support the achievement of sustained success by a quality management approach. It is applicable to any organization, regardless of size, type and activity.

ISO 9004:2009 is not intended for certification, regulatory or contractual use.

In this guide, to further enhance the learner's understanding of Quality Management, an attempt was made to link the relevant clauses of ISO 9001:2015 with the complimentary clause in ISO9004:2009.

2 ISO 9001:2015

2.1 ISO 9001:2015 DEVELOPMENT TIMELINE

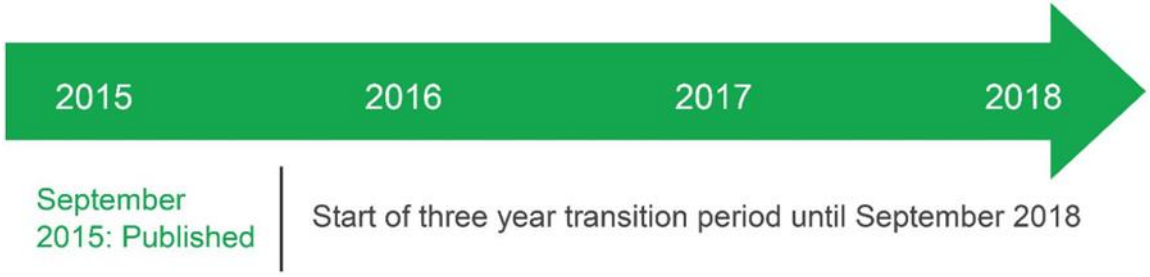


Figure 2: ISO 9001:2015 development timeline

2.2 ISO 9001:2015 IMPLEMENTATION TIMELINE

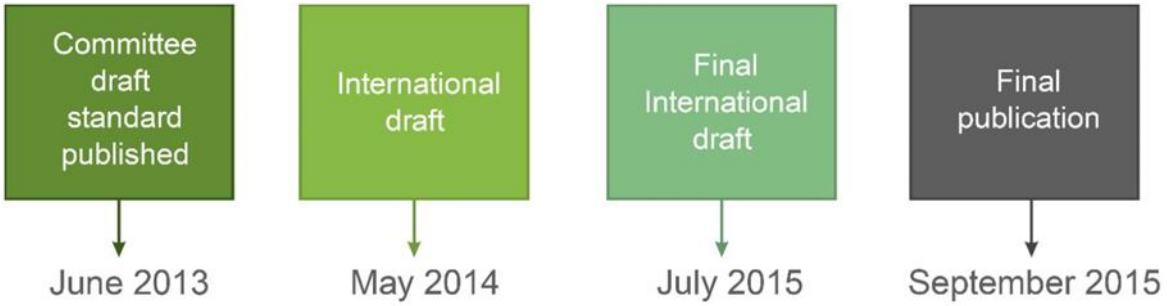


Figure 3: ISO 9001:2015 implementation timeline

Need for Change

Changes to ISO 9001 were needed to:

- fulfil the requirement of periodic review of standards
- maintain relevance
- integrate with other management systems
- provide an integrated approach to organisational management
- provide a consistent foundation for the next 10 years
- reflect the increasingly complex environments in which organisations operate
- ensure the new standard reflects the needs of all potential user groups
- enhance an organisation's ability to satisfy its customers

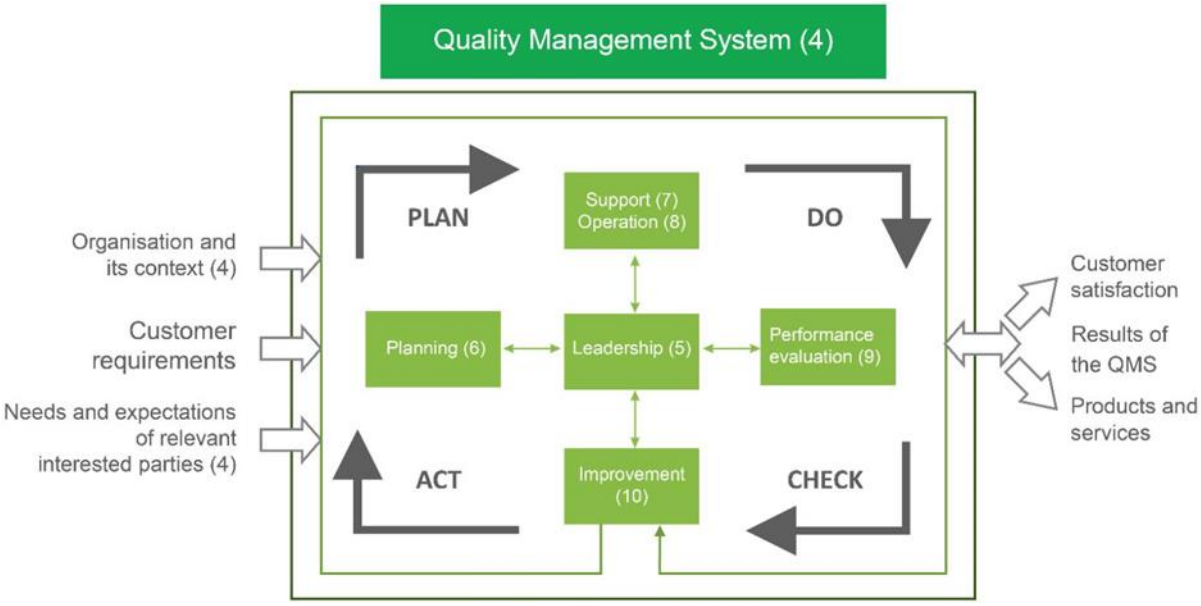


Figure 4: Quality Management System – Deming Cycle

ISO 9001:2015 Deming Cycle

The Plan-Do-Check-Act (PDCA) or Deming Cycle can be applied to all processes and to the QMS as a whole. Figure 4 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

The PDCA cycle can be briefly described as follows:

Plan: (Clause 6)

Establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organisation's policies, and identify and address risks and opportunities.

Do: (Clauses 7, 8)

Implement what was planned.

Check: (Clause 9)

Monitor and, where applicable, measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results.

Act: (Clause 10)

Take action to improve performance, as necessary

Summary of Key Changes to ISO 9001:2015

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

- the adoption of the high-level structure and terminology as set out in Annex SL
- explicit requirements for risk-based thinking in combination with the process approach
- fewer prescribed requirements
- less emphasis on documents
- improved applicability for services
- increased emphasis on organisational context • increased leadership requirements
- greater emphasis on achieving desired outcomes to improve customer satisfaction.

2.3 ELEMENTS OF ISO 9001:2015

CLAUSE NO	CLAUSE TITLE
4	**Context of the organisation (Title only)**
4.1	Understanding the organisation and its context
4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of QMS
4.4	QMS and its processes
5	**Leadership (Title only)**
5.1	Leadership and commitment (Title only)
5.1.1	General
5.1.2	Customer focus
5.2	Policy (Title only)
5.2.1	Establishing the quality policy
5.2.2	Communicating the quality policy
5.3	Organisational roles, responsibilities, authorities
6	**Planning (Title only)**
6.1	Actions to address risks and opportunities
6.2	Quality objectives and planning to achieve them
6.3	Planning of changes
7	**Support (Title only)**
7.1	Resources (Title only)
7.1.1	General
7.1.2	People
7.1.3	Infrastructure
7.1.4	Environment for the operation of processes
7.1.5	Monitoring and measuring resources (Title only)
7.1.5.1	General
7.1.5.2	Measurement traceability
7.1.6	Organisational knowledge

7.2	Competence
7.3	Awareness
7.4	Communication
7.5	Documented Information (Title only)
7.5.1	General
7.5.2	Creating and updating documents
7.5.3	Control of documented information
8	**Operation (Title only)**
8.1	Operational planning and control
8.2	Requirements for products and services (Title only)
8.2.1	Customer communication
8.2.2	Determining the requirements for products and services
8.2.3	Review of the requirements for products and services
8.2.4	Changes to requirements for products and services
8.3	Design and development of products and services (Title only)
8.3.1	General
8.3.2	Design and development planning
8.3.3	Design and development inputs
8.3.4	Design and development controls
8.3.5	Design and development outputs
8.3.6	Design and development changes
8.4	Control of externally provided processes, products and services (Title only)
8.4.1	General
8.4.2	Type and extent of control
8.4.3	Information for external providers
8.5	Production and service provision (Title only)
8.5.1	Control of production and service provision
8.5.2	Identification and traceability
8.5.3	Property belonging to customers or external providers

2.4 TERMS AND DEFINITIONS OF ISO 9001:2015

The terms and definitions for ISO 9001:2015 are found in ISO 9000:2015 and are referenced in this guide verbatim.

3.1 Terms Related to A Person or People

3.1.1 Top Management

A person or group of people who directs and controls an organisation (3.2.1) at the highest level.

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organisation.

Note 2 to entry: If the scope of the management system (3.5.3) covers only part of an organisation, then top management refers to those who direct and control that part of the organisation.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.1.2 Quality Management System Consultant

A person who assists the organisation (3.2.1) on quality management system realisation (3.4.3), giving advice or information (3.8.2).

Note 1 to entry: The quality management system consultant can also assist in realising parts of a quality management system (3.5.4).

Note 2 to entry: ISO 10019:2005 provides guidance on how to distinguish a competent quality management system consultant from one who is not competent.

3.1.3 Involvement

Taking part in an activity, event or situation.

3.1.4 Engagement

Involvement (3.1.3) in, and contribution to, activities to achieve shared objectives (3.7.1).

3.1.5 Configuration Authority, Configuration Control Board, Dispositioning Authority

A person or a group of persons with assigned responsibility and authority to make decisions on the configuration (3.10.6).

Note 1 to entry: Relevant interested parties (3.2.3) within and outside the organisation (3.2.1) should be represented on the configuration authority.

3.1.6 Dispute Resolver

Individual person assigned by a DRP-provider (3.2.7) to assist the parties in resolving a dispute (3.9.6).

Example: Staff, volunteer, contract (3.4.7) personnel.

3.2 Terms Related to an Organisation

3.2.1 Organisation

A person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (3.7.1).

Note 1 to entry: The concept of organisation includes, but is not limited to, sole trader, company, corporation, firm, enterprise, authority, partnership, association (3.2.8), charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 1 to entry.

3.2.2 Context of The Organisation

A combination of internal and external issues that can have an effect on an organisation's (3.2.1) approach to developing and achieving its objectives (3.7.1).

Note 1 to entry: The organisation's objectives can be related to its products (3.7.6) and services (3.7.7), investments and behaviour towards its interested parties (3.2.3).

Note 2 to entry: The concept of context of the organisation is equally applicable to not-for-profit or public service organisations as it is to those seeking profits.

Note 3 to entry: In English, this concept is often referred to by other terms such as "business environment", "organisational environment" or "ecosystem of an organisation".

Note 4 to entry: Understanding the infrastructure (3.5.2) can help to define the context of the organisation.

3.2.3 Interested Party, Stakeholder

A person or organisation (3.2.1) that can affect, be affected by, or perceive itself to be affected by, a decision or activity.

Example: Customers (3.2.4), owners, people in an organisation, providers (3.2.5), bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding the example.

3.2.4 Customer

A person or organisation (3.2.1) that could or does receive a product (3.7.6) or a service (3.7.7) that is intended for or required by this person or organisation.

Example: Consumer, client, end-user, retailer, receiver of product or service from an internal process (3.4.1), beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the organisation.

3.2.5 Provider, Supplier

An organisation (3.2.1) that provides a product (3.7.6) or a service (3.7.7).

Example: Producer, distributor, retailer or vendor of a product or a service.

Note 1 to entry: A provider can be internal or external to the organisation.

Note 2 to entry: In a contractual situation, a provider is sometimes called "contractor".

3.2.6 External Provider, External Supplier

A provider (3.2.5) that is not part of the organisation (3.2.1).

Example: Producer, distributor, retailer or vendor of a product (3.7.6) or a service (3.7.7)

3.2.7 DRP-Provider, Dispute Resolution Process Provider.

A person or organisation (3.2.1) that supplies and operates an external dispute (3.9.6) resolution process (3.4.1)

Note 1 to entry: Generally, a DRP-provider is a legal entity, separate from the organisation or person as an individual and the complainant. In this way, the attributes of independence and fairness are emphasised. In some situations, a separate unit is established within the organisation to handle unresolved complaints (3.9.3).

Note 2 to entry: The DRP-provider contracts (3.4.7) with the parties to provide dispute resolution and is accountable for performance (3.7.8). The DRP-provider supplies dispute resolvers (3.1.6). The DRP- provider also utilises support, executive and other managerial staff to supply financial resources, clerical support, scheduling assistance, training, meeting rooms, supervision and similar functions.

Note 3 to entry: DRP-providers can take many forms including not-for-profit, for-profit and public entities. An association (3.2.8) can also be a DRP-provider.

Note 4 to entry: In ISO 10003:2007 instead of the term DRP-provider, the term "provider" is used.

3.2.8 Association

An organisation (3.2.1) consisting of member organisations or persons.

3.2.9 Metrological Function

A functional unit with administrative and technical responsibility for defining and implementing the measurement management system (3.5.7).

3.3 Terms Related to Activity

3.3.1 Improvement

Activity to enhance performance (3.7.8).

Note 1 to entry: The activity can be recurring or singular.

3.3.2 Continual Improvement

Recurring activity to enhance performance (3.7.8).

Note 1 to entry: The process (3.4.1) of establishing objectives (3.7.1) and finding opportunities for improvement (3.3.1) is a continual process through the use of audit findings (3.13.9) and audit conclusions (3.13.10), analysis of data (3.8.1), management (3.3.3) reviews (3.11.2) or other means and generally leads to corrective action (3.12.2) or preventive action (3.12.1).

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.3.3 Management

Co-ordinated activities to direct and control an organisation (3.2.1).

Note 1 to entry: Management can include establishing policies (3.5.8), objectives (3.7.1), and processes (3.4.1) to achieve these objectives.

Note 2 to entry: The word "management" sometimes refers to people, that is, a person or group of people with authority and responsibility for the conduct and control of an organisation. When "management" is used in this sense, it should always be used with some form of qualifier to avoid confusion with the concept of "management" as a set of activities defined above. For example, "management shall…" is deprecated whereas "top management (3.1.1) shall…" is acceptable.
Otherwise, different words should be adopted to convey the concept when related to people, for example, managerial or managers.

3.3.4 Quality Management

Management (3.3.3) with regard to quality (3.6.2).

Note 1 to entry: Quality management can include establishing quality policies (3.5.9) and quality objectives (3.7.2), and processes (3.4.1) to achieve these quality objectives through quality planning (3.3.5), quality assurance (3.3.6), quality control (3.3.7), and quality improvement (3.3.8).

3.3.5 Quality Planning

Part of quality management (3.3.4) focussed on setting quality objectives 3.7.2) and specifying necessary operational processes (3.4.1), and related resources to achieve the quality objectives.

Note 1 to entry: Establishing quality plans (3.8.9) can be part of quality planning.

3.3.6 Quality Assurance

Part of quality management (3.3.4) focussed on providing confidence that quality requirements (3.6.5) will be fulfilled.

3.3.7 Quality Control

Part of quality management (3.3.4) focussed on fulfilling quality requirements (3.6.5)

3.3.8 Quality Improvement

Part of quality management (3.3.4) focussed on increasing the ability to fulfil quality requirements (3.6.5)

Note 1 to entry: The quality requirements can be related to any aspect such as effectiveness (3.7.11), efficiency (3.7.10) or traceability (3.6.13).

3.3.9 Configuration Management

Co-ordinated activities to direct and control configuration (3.10.6).

Note 1 to entry: Configuration management generally concentrates on technical and organisational activities that establish and maintain control of a product (3.7.6) or service (3.7.7) and its product configuration information (3.6.8) throughout the life cycle of the product.

3.3.10 Change Control

Activities for control of the output (3.7.5) after formal approval of its product configuration information (3.6.8).

3.3.11 Activity

The smallest identified object of work in a project (3.4.2).

3.3.12 Project Management

Planning, organising, monitoring (3.11.3), controlling and reporting of all aspects of a project (3.4.2), and the motivation of all those involved in it to achieve the project objectives.

3.3.13 Configuration Object

An object (3.6.1) within a configuration (3.10.6) that satisfies an end-use function.

3.4 Terms Related to Process

3.4.1 Process

A set of interrelated or interacting activities that use inputs to deliver an intended result.

Note 1 to entry: Whether the "intended result" of a process is called output (3.7.5), product (3.7.6) or service (3.7.7) depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

Note 4 to entry: Processes in an organisation (3.2.1) are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the conformity (3.6.11) of the resulting output cannot be readily or economically validated is frequently referred to as a "special process".

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified to prevent circularity between process and output, and Notes 1 to 5 to entry have been added.

3.4.2 Project

A unique process (3.4.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective (3.7.1) conforming to specific requirements (3.6.4), including the constraints of time, cost and resources.

Note 1 to entry: An individual project can form part of a larger project structure and generally has a defined start and finish date.

Note 2 to entry: In some projects the objectives and scope are updated and the product (3.7.6) or service (3.7.7) characteristics (3.10.1) defined progressively as the project proceeds.

Note 3 to entry: The output (3.7.5) of a project can be one or several units of product or service.

Note 4 to entry: The project's organisation (3.2.1) is normally temporary and established for the lifetime of the project.

Note 5 to entry: The complexity of the interactions among project activities is not necessarily related to the project size.

3.4.3 Quality Management System Realisation

A process (3.4.1) of establishing, documenting, implementing, maintaining and continually improving a quality management system (3.5.4).

[**Source:** ISO 10019:2005, 3.1, modified – Notes have been deleted]

3.4.4 Competence Acquisition

A process (3.4.1) of attaining competence (3.10.4).

[**Source:** ISO 10018:2012, 3.2, modified]

3.4.5 Procedure

A specified way to carry out an activity or a process (3.4.1).

Note 1 to entry: Procedures can be documented or not.

3.4.6 Outsource (Verb)

To make an arrangement where an external organisation (3.2.1) performs part of an organisation's function or process (3.4.1).

Note 1 to entry: An external organisation is outside the scope of the management system (3.5.3), although the outsourced function or process is within the scope.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.4.7 Contract

A binding agreement

3.4.8 Design and Development

A set of processes (3.4.1) that transform requirements (3.6.4) for an object (3.6.1) into more detailed requirements for that object.

Note 1 to entry: The requirements forming input to design and development are often the result of research and can be expressed in a broader, more general sense than the requirements forming the output (3.7.5) of design and development. The requirements are generally defined in terms of characteristics (3.10.1). In a project (3.4.2), there can be several design and development stages.

Note 2 to entry: In English, the words "design" and "development" and the term "design and development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development. In French, the words "conception" and "development" and the term "conception et development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development.

Note 3 to entry: A qualifier can be applied to indicate the nature of what is being designed and developed (for example, product (3.7.6) design and development, service (3.7.7) design and development or process design and development).

3.5 Terms related to system

3.5.1 System

A set of interrelated or interacting elements.

3.5.2 Infrastructure

A system (3.5.1) of facilities, equipment and services (3.7.7) needed for the operation of an organisation (3.2.1).

3.5.3 Management System

A set of interrelated or interacting elements of an organisation (3.2.1) to establish policies (3.5.8) and objectives (3.7.1), and processes (3.4.1) to achieve those objectives.

Note 1 to entry: A management system can address a single discipline or several disciplines, for example, quality management (3.3.4), financial management or environmental management.

Note 2 to entry: The management system elements establish the organisation's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

Note 3 to entry: The scope of a management system can include the whole of the organisation, specific and identified functions of the organisation, specific and identified sections of the organisation, or one or more functions across a group of organisations.

Note 4 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Notes 1 to 3 to entry.

3.5.4 Quality Management System

Part of a management system (3.5.3) with regard to quality (3.6.2).

3.5.5 Work Environment

A set of conditions under which work is performed.

Note 1 to entry: Conditions can include physical, social, psychological and environmental factors (such as temperature, lighting, recognition schemes, occupational stress, ergonomics and atmospheric composition).

3.5.6 Metrological Confirmation

A set of operations required to ensure that measuring equipment (3.11.6) conforms to the requirements (3.6.4) for its intended use.

Note 1 to entry: Metrological confirmation generally includes calibration or verification (3.8.12), any necessary adjustment or repair (3.12.9), and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labelling.

Note 2 to entry: Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented.

Note 3 to entry: The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

Note 4 to entry: Metrological requirements are usually distinct from, and are not specified in, product (3.7.6) requirements.

[**Source:** ISO 10012:2003, 3.5, modified – Note 1 to entry has been modified]

3.5.7 Measurement Management System

A set of interrelated or interacting elements necessary to achieve metrological confirmation (3.5.6) and control of measurement processes (3.11.5).

[**Source:** ISO 10012:2003, 3.1, modified]

3.5.8 Policy

Intentions and direction of an organisation (3.2.1) as formally expressed by its top management (3.1.1).

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.5.9 Quality Policy

Policy (3.5.8) related to quality (3.6.2).

Note 1 to entry: Generally, the quality policy is consistent with the overall policy of the organisation (3.2.1), can be aligned with the organisation's vision (3.5.10) and mission (3.5.11) and provides a framework for the setting of quality objectives (3.7.2).

Note 2 to entry: Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy.

3.5.10 Vision

Aspiration of what an organisation (3.2.1) would like to become as expressed by top management (3.1.1).

3.5.11 Mission

The organisation's (3.2.1) purpose for existing as expressed by top management (3.1.1).

3.5.12 Strategy

A plan to achieve a long-term or overall objective (3.7.1).

3.6 Terms Related to Requirement

3.6.1 Object, Entity, Item

Anything perceivable or conceivable.

Example: A product (3.7.6), service (3.7.7), process (3.4.1), person, organisation (3.2.1), system (3.5.1), resource.

Note 1 to entry: Objects can be material (for example, an engine, a sheet of paper, a diamond), non-material (for example, conversion ratio, a project plan) or imagined (for example, the future state of the organisation).

[**Source:** ISO 1087-1:2000, 3.1.1, modified]

3.6.2 Quality

The degree to which a set of inherent characteristics (3.10.1) of an object (3.6.1) fulfils requirements (3.6.4).

Note 1 to entry: The term "quality" can be used with adjectives such as poor, good or excellent

Note 2 to entry: "Inherent", as opposed to "assigned", means existing in the object (3.6.1).

3.6.3 Grade

A category or rank given to different requirements (3.6.4) for an object (3.6.1) having the same functional use.

Example: Class of airline ticket and category of hotel in a hotel brochure.

Note 1 to entry: When establishing a quality requirement (3.6.5), the grade is generally specified.

3.6.4 Requirement

A need or expectation that is stated, generally implied or obligatory.

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organisation (3.2.1) and interested parties (3.2.3) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information (3.8.6).

Note 3 to entry: A qualifier can be used to denote a specific type of requirement, for example, product (3.7.6) requirement, quality management (3.3.4) requirement, customer (3.2.4) requirement, quality requirement (3.6.5).

Note 4 to entry: Requirements can be generated by different interested parties or by the organisation itself.

Note 5 to entry: It can be necessary for achieving high customer satisfaction (3.9.2) to fulfil an expectation of a customer even if it is neither stated nor generally implied or obligatory.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Notes 3 to 5 to entry.

3.6.5 Quality Requirement

A requirement (3.6.4) related to quality (3.6.2).

3.6.6 Statutory Requirement

Obligatory requirement (3.6.4) specified by a legislative body.

3.6.7 Regulatory Requirement

Obligatory requirement (3.6.4) specified by an authority mandated by a legislative body.

3.6.8 Product Configuration Information

A requirement (3.6.4) or other information for product (3.7.6) design, realisation, verification (3.8.12), operation and support.

[**Source:** ISO 10007:2003, 3.9, modified]

3.6.9 Nonconformity

Non-fulfilment of a requirement (3.6.4).

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.6.10 Defect

Nonconformity (3.6.9) related to an intended or specified use.

Note 1 to entry: The distinction between the concepts defect and nonconformity is important as it has legal connotations; particularly those associated with product (3.7.6) and service (3.7.7) liability issues.

Note 2 to entry: The intended use as intended by the customer (3.2.4) can be affected by the nature of the information (3.8.2), such as operating or maintenance instructions, provided by the provider (3.2.5).

3.6.11 Conformity

Fulfilment of a requirement (3.6.4).

Note 1 to entry: In English the word "conformance" is synonymous but deprecated. In French, the word "compliance" is synonymous but deprecated.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.6.12 Capability

Ability of an object (3.6.1) to realise an output (3.7.5) that will fulfil the requirements (3.6.4) for that output.

Note 1 to entry: Process (3.4.1) capability terms in the field of statistics are defined in ISO 3534-2.

3.6.13 Traceability

Ability to trace the history, application or location of an object (3.6.1).

Note 1 to entry: When considering a product (3.7.6) or a service (3.7.7), traceability can relate to: the origin of materials and parts; the processing history; the distribution and location of the product or service after delivery.

Note 2 to entry: In the field of metrology, the definition in ISO/IEC Guide 99 is the accepted definition.

3.6.14 Dependability

Ability to perform as and when required.

[**Source:** IEC 60050-192, modified – Notes have been deleted]

3.6.15 Innovation

A new or changed object (3.6.1) realising or redistributing value.

Note 1 to entry: Activities resulting in innovation are generally managed.

Note 2 to entry: Innovation is generally significant in its effect.

3.7 Terms Related to Result

3.7.1 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 objectives) and can apply at different levels (such as strategic, organisation (3.2.1)-wide, project (3.4.2), product (3.7.6) and process (3.4.1).

Note 3 to entry: An objective can be expressed in other ways, for example, as an intended outcome, a purpose, an operational criterion, as a quality objective (3.7.2) or by the use of other words with similar meaning (for example, aim, goal, or target).

Note 4 to entry: In the context of quality management systems (3.5.4) quality objectives (3.7.2) are set by the organisation (3.2.1), consistent with the quality policy (3.5.9), to achieve specific results.

Note 5 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 2 to entry.

3.7.2 Quality Objective

Objective (3.7.1) related to quality (3.6.2).

Note 1 to entry: Quality objectives are generally based on the organisation's (3.2.1) quality policy (3.5.9).

Note 2 to entry: Quality objectives are generally specified for relevant functions, levels and processes (3.4.1) in the organisation (3.2.1).

3.7.3 Success

Achievement of an objective (3.7.1).

Note 1 to entry: The success of an organisation (3.2.1) emphasises the need for a balance between its economic or financial interests and the needs of its interested parties (3.2.3), such as customers (3.2.4), users, investors/shareholders (owners), people in the organisation, providers (3.2.5), partners, interest groups and communities.

3.7.4 Sustained Success

Success (3.7.3) over a period.

Note 1 to entry: Sustained success emphasises the need for a balance between the economic-financial interests of an organisation (3.2.1) and those of the social and ecological environment.

Note 2 to entry: Sustained success relates to the interested parties (3.2.3) of an organisation, such as customers (3.2.4), owners, people in an organisation, providers (3.2.5), bankers, unions, partners or society.

3.7.5 Output

Result of a process (3.4.1)

Note 1 to entry: Whether an output of the organisation (3.2.1) is a product (3.7.6) or a service (3.7.7) depends on the preponderance of the characteristics (3.10.1) involved, for example, a painting for sale in a gallery is a product, whereas supply of a commissioned painting is a service; a hamburger bought in a retail store is a product, whereas receiving an order and serving a hamburger ordered in a restaurant is part of a service.

3.7.6 Product

Output (3.7.5) of an organisation (3.2.1) that can be produced without any transaction-taking place between the organisation and the customer (3.2.4).

Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between provider (3.2.5) and customer, but can often involve this service (3.7.7) element upon its delivery to the customer.

Note 2 to entry: The dominant element of a product is that it is generally tangible.

Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (3.10.1) (for example, tyres). Processed materials are tangible and their amount is a continuous characteristic (for example, fuel and soft drinks). Hardware and processed materials are often referred to as goods.
Software consists of information (3.8.2) regardless of delivery medium (for example, computer programme, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license).

3.7.7 Service

Output (3.7.5) of an organisation (3.2.1) with at least one activity necessarily performed between the organisation and the customer (3.2.4).

Note 1 to entry: The dominant elements of a service are generally intangible.

Note 2 to entry: Service often involves activities at the interface with the customer to establish customer requirements (3.6.4) as well as upon delivery of the service and can involve a continuing relationship such as banks, accountancies or public organisations, for example, schools or hospitals.

Note 3 to entry: Provision of a service can involve, for example, the following: an activity performed on a customer-supplied tangible product (3.7.6) (for example, a car to be repaired); an activity performed on a customer-supplied intangible product (for example, the income statement needed to prepare a tax return); the delivery of an intangible product (for example, the delivery of information (3.8.2) in the context of knowledge transmission); the creation of ambience for the customer (for example, in hotels and restaurants);

Note 4 to entry: A service is generally experienced by the customer.

3.7.8 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 (3.3.3) of activities (3.3.11), processes (3.4.1), products (3.7.6), services (3.7.7), systems (3.5.1) or organisations (3.2.1).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 2 to entry.

3.7.9 Risk

Effect of uncertainty.

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 (3.8.2) related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterised 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 word "risk" is sometimes used when there is the possibility of only negative consequences.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 5 to entry.

3.7.10 Efficiency

The relationship between the result achieved and the resources used.

3.7.11 Effectiveness

The extent to which planned activities are realised and planned results are achieved.

Note 1to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding "are" before "achieved".

3.8 Terms Related to Data, Information and Document

3.8.1 Data

Facts about an object (3.6.1).

3.8.2 Information

Meaningful data (3.8.1).

3.8.3 Objective Evidence

Data (3.8.1) supporting the existence or verity of something.

Note 1 to entry: Objective evidence can be obtained through observation, measurement (3.11.4), test (3.11.8), or by other means.

Note 2 to entry: Objective evidence for the purpose of audit (3.13.1) generally consists of records (3.8.10), statements of fact or other information (3.8.2) which are relevant to the audit criteria (3.13.7) and verifiable.

3.8.4 Information System

A network of communication channels used within an organisation (3.2.1)

3.8.5 Document

Information (3.8.2) and the medium in which it is contained.

Example: A record (3.8.10), specification (3.8.7), procedure document, drawing, report, standard.

Note 1 to entry: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.

Note 2 to entry: A set of documents, for example specifications and records, is frequently called "documentation".

Note 3 to entry: Some requirements (3.6.4) (for example, the requirement to be readable) relate to all types of documents. However, there can be different requirements for specifications (for example, the requirement to be revision controlled) and for records (for example, the requirement to be retrievable).

3.8.6 Documented Information

Information (3.8.2) required to be controlled and maintained by an organisation (3.2.1) 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 management system (3.5.3), including related processes (3.4.1); information created in order for the organisation to operate (documentation); evidence of results achieved (records (3.8.10)).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.8.7 Specification

A document (3.8.5) stating requirements (3.6.4).

Example: A quality manual (3.8.8), quality plan (3.8.9), technical drawing, procedure document, work instruction.

Note 1 to entry: A specification can be related to activities (for example, procedure document, process (3.4.1) specification and test (3.11.8) specification), or products (3.7.6) (for example, product specification, performance (3.7.8) specification and drawing).

Note 2 to entry: It can be that, by stating requirements, a specification additionally is stating results achieved by design and development (3.4.8) and thus in some cases can be used as a record (3.8.10).

3.8.8 Quality Manual

Specification (3.8.7) for the quality management system (3.5.4) of an organisation (3.2.1).

Note 1 to entry: Quality manuals can vary in detail and format to suit the size and complexity of an individual organisation (3.2.1).

3.8.9 Quality Plan

Specification (3.8.7) of the procedures (3.4.5) and associated resources to be applied when and by whom to a specific object (3.6.1).

Note 1 to entry: These procedures generally include those referring to quality management (3.3.4) processes (3.4.1) and to product (3.7.6) and service (3.7.7) realisation processes.

Note 2 to entry: A quality plan often refers to parts of the quality manual (3.8.8) or to procedure documents (3.8.5).

Note 3 to entry: A quality plan is generally one of the results of quality planning (3.3.5).

3.8.10 Record

A document (3.8.5) stating results achieved or providing evidence of activities performed.

Note 1 to entry: Records can be used, for example, to formalise traceability (3.6.13) and to provide evidence of verification (3.8.12), preventive action (3.12.1) and corrective action (3.12.2).

Note 2 to entry: Generally, records need not be under revision control.

3.8.11 Project Management Plan

A document (3.8.5) specifying what is necessary to meet the objective(s) (3.7.1) of the project (3.4.2).

Note 1 to entry: A project management plan should include or refer to the project's quality plan (3.8.9).

Note 2 to entry: The project management plan also includes or references such other plans as those relating to organisational structures, resources, schedule, budget, risk (3.7.9) management (3.3.3), environmental management, health and safety management, and security management, as appropriate.

[**Source:** ISO 10006:2003, 3.7]

3.8.12 Verification

Confirmation, through the provision of objective evidence (3.8.3), that specified requirements (3.6.4) have been fulfilled.

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection (3.11.7) or of other forms of determination (3.11.1) such as performing alternative calculations or reviewing documents (3.8.5).

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process (3.4.1).

Note 3 to entry: The word "verified" is used to designate the corresponding status.

3.8.13 Validation

Confirmation, through the provision of objective evidence (3.8.3), that the requirements (3.6.4) for a specific intended use or application have been fulfilled.

Note 1 to entry: The objective evidence needed for a validation is the result of a test (3.11.8) or other form of determination (3.11.1) such as performing alternative calculations or reviewing documents (3.8.5).

Note 2 to entry: The word "validated" is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

3.8.14 Configuration Status Accounting

Formalised recording and reporting of product configuration information (3.6.8), the status of proposed changes and the status of the implementation of approved changes.

[**Source:** ISO 10007:2003, 3.7]

3.8.15 Specific Case

The subject of the quality plan (3.8.9).

Note 1 to entry: This term is used to avoid repetition of "process (3.4.1), product (3.7.6), project (3.4.2) or contract (3.4.7)" within ISO 10005.

[**Source:** ISO 10005:2005, 3.10, modified – Note 1 to entry has been modified]

3.9 Terms Related to Customer

3.9.1 Feedback

Opinions, comments and expressions of interest in a product (3.7.6), a service (3.7.7) or a complaints-handling process (3.4.1).

[**Source:** ISO 10002:2014, 3.6, modified – The term "service" has been included in the definition]

3.9.2 Customer Satisfaction

Customers (3.2.4) perception of the degree to which the customer's expectations have been fulfilled.

Note 1 to entry: It can be that the customer's expectation is not known to the organisation (3.2.1), or even to the customer in question, until the product (3.7.6) or service (3.7.7) is delivered. It can be necessary for achieving high customer satisfaction to fulfil an expectation of a customer even if it is neither stated nor generally implied or obligatory.

Note 2 to entry: Complaints (3.9.3) are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

Note 3 to entry: Even when customer requirements (3.6.4) have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

[**Source:** ISO 10004:2012, 3.3, modified – Notes have been modified]

3.9.3 Complaint

Expression of dissatisfaction made to an organisation (3.2.1), related to its product (3.7.6) or service (3.7.7), or the complaints-handling process (3.4.1) itself, where a response or resolution is explicitly or implicitly expected.

[**Source:** ISO 10002:2014, 3.2, modified – The term "service" has been included in the definition]

3.9.4 Customer Service

Interaction of the organisation (3.2.1) with the customer (3.2.4) throughout the life cycle of a product (3.7.6) or a service (3.7.7).

[**Source:** ISO 10002:2014, 3.5, modified – The term "service" has been included in the definition]

3.9.5 Customer Satisfaction Code of Conduct

Promises, made to customers (3.2.4) by an organisation (3.2.1) concerning its behaviour, that are aimed at enhanced customer satisfaction (3.9.2) and related provisions.

Note 1 to entry: Related provisions can include objectives (3.7.1), conditions, limitations, contact information (3.8.2), and complaints (3.9.3) handling procedures (3.4.5).

Note 2 to entry: In ISO 10001:2007, the term "code" is used instead of "customer satisfaction code of conduct".

[**Source:** ISO 10001:2007, 3.1, modified – The term "code" has been removed as an admitted term, and Note 2 to entry has been modified]

3.9.6 Dispute

Disagreement, arising from a complaint (3.9.3), submitted to a *DRP*-provider (3.2.7).

Note 1 to entry: Some organisations (3.2.1) allow their customers (3.2.4) to express their dissatisfaction to a DRP-provider in the first instance. In this situation, the expression of dissatisfaction becomes a complaint when sent to the organisation for a response and becomes a dispute if not resolved by the organisation without DRP-provider intervention. Many organisations prefer their customers to first express any dissatisfaction to the organisation before utilising dispute resolution external to the organisation.

[**Source:** ISO 10003:2007, 3.6, modified]

3.10 Terms Related to Characteristic

3.10.1 Characteristic

A distinguishing feature.

Note 1 to entry: A characteristic can be inherent or assigned.

Note 2 to entry: A characteristic can be qualitative or quantitative.

Note 3 to entry: There are various classes of characteristic, such as the following:

- physical (for example, mechanical, electrical, chemical or biological characteristics);
- sensory (for example, related to smell, touch, taste, sight, hearing);
- behavioural (for example, courtesy, honesty, veracity);
- temporal (for example, punctuality, reliability, availability, continuity);
- ergonomic (for example, physiological characteristic, or related to human safety);
- functional (for example, maximum speed of an aircraft).

3.10.2 Quality Characteristic

An inherent characteristic (3.10.1) of an object (3.6.1) related to a requirement (3.6.4).

Note 1 to entry: Inherent means existing in something, especially as a permanent characteristic.

Note 2 to entry: A characteristic assigned to an object (for example, the price of an object) is not a quality characteristic of that object.

3.10.3 Human Factor

A characteristic (3.10.1) of a person having an impact on an object (3.6.1) under consideration.

Note 1 to entry: Characteristics can be physical, cognitive or social.

Note 2 to entry: Human factors can have a significant impact on a management system (3.5.3).

3.10.4 Competence

Ability to apply knowledge and skills to achieve intended results.

Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.10.5 Metrological Characteristic

A characteristic (3.10.1) which can influence the results of measurement (3.11.4).

Note 1 to entry: Measuring equipment (3.11.6) usually has several metrological characteristics.

Note 2 to entry: Metrological characteristics can be the subject of calibration.

3.10.6 Configuration

Interrelated functional and physical characteristics (3.10.1) of a product (3.7.6) or service (3.7.7) defined in product configuration information (3.6.8).

[**Source:** ISO 10007:2003, 3.3, modified – The term "service" has been included in the definition]

3.10.7 Configuration Baseline

Approved product configuration information (3.6.8) that establishes the characteristics (3.10.1) of a product (3.7.6) or service (3.7.7) at a point in time that serves as reference for activities throughout the life cycle of the product or service.

[**Source:** ISO 10007:2003, 3.4, modified – The term "service" has been included in the definition]

3.11 Terms Related to Determination

3.11.1 Determination

Activity to find out one or more characteristics (3.10.1) and their characteristic values.

3.11.2 Review

Determination (3.11.1) of the suitability, adequacy or effectiveness (3.7.11) of an object (3.6.1) to achieve established objectives (3.7.1).

Example: Management review, design and development (3.4.8) review, review of customer (3.2.4) requirements (3.6.4), review of corrective action (3.12.2) and peer review.

Note 1 to entry: Review can also include the determination of efficiency (3.7.10).

3.11.3 Monitoring

Determining (3.11.1) the status of a system (3.5.1), a process (3.4.1), a product (3.7.6), a service (3.7.7), or an activity.

Note 1 to entry: For the determination of the status, there can be a need to check, supervise or critically observe.

Note 2 to entry: Monitoring is generally a determination of the status of an object (3.6.1), carried out at different stages or at different times.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition and Note 1 to entry have been modified and Note 2 to entry has been added.

3.11.4 Measurement

Process (3.4.1) to determine a value.

Note 1 to entry: According to ISO 3534-2, the value determined is generally the value of a quantity.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.11.5 Measurement Process

A set of operations to determine the value of a quantity.

3.11.6 Measuring Equipment

Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realise a measurement process (3.11.5).

3.11.7 Inspection

Determination (3.11.1) of conformity (3.6.11) to specified requirements (3.6.4).

Note 1 to entry: If the result of an inspection shows conformity, it can be used for purposes of verification (3.8.12).

Note 2 to entry: The result of an inspection can show conformity or nonconformity (3.6.9) or a degree of conformity.

3.11.8 Test

Determination (3.11.1) according to requirements (3.6.4) for a specific intended use or application.

Note 1 to entry: If the result of a test shows conformity (3.6.11), it can be used for purposes of validation (3.8.13).

3.11.9 Progress Evaluation

Assessment of progress made on achievement of the project (3.4.2) objectives (3.7.1).

Note 1 to entry: This assessment should be carried out at appropriate points in the project life cycle across project processes (3.4.1), based on criteria for project processes and product (3.7.6) or service (3.7.7).

Note 2 to entry: The results of progress evaluations can lead to revision of the project management plan (3.8.11).

[**Source:** ISO 10006:2003, 3.4, modified – Notes to entry have been modified]

3.12 Terms Related to Action

3.12.1 Preventive Action

Action to eliminate the cause of a potential nonconformity (3.6.9) or other potential undesirable situation.

Note 1 to entry: There can be more than one cause for a potential nonconformity.

Note 2 to entry: Preventive action is taken to prevent occurrence whereas corrective action (3.12.2) is taken to prevent recurrence.

3.12.2 Corrective Action

Action to eliminate the cause of a nonconformity (3.6.9) and to prevent recurrence.
Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action (3.12.1) is taken to prevent occurrence.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Notes 1 and 2 to entry.

3.12.3 Correction

Action to eliminate a detected nonconformity (3.6.9).

Note 1 to entry: A correction can be made in advance of, in conjunction with or after a corrective action (3.12.2).

Note 2 to entry: A correction can be, for example, rework (3.12.8) or regrade (3.12.4).

3.12.4 Regrade

Alteration of the grade (3.6.3) of a nonconforming (3.6.9) product (3.7.6) or service (3.7.7) in order to make it conform to requirements (3.6.4) differing from the initial requirements.

3.12.5 Concession

Permission to use or release (3.12.7) a product (3.7.6) or service (3.7.7) that does not conform to specified requirements (3.6.4).

Note 1 to entry: A concession is generally limited to the delivery of products and services that have nonconforming (3.6.9) characteristics (3.10.1) within specified limits and is generally given for a limited quantity of products and services or period, and for a specific use.

3.12.6 Deviation Permit

Permission to depart from the originally specified requirements (3.6.4) of a product (3.7.6) or service (3.7.7) prior to its realisation.

Note 1 to entry: A deviation permit is generally given for a limited quantity of products and services or period, and for a specific use.

3.12.7 Release

Permission to proceed to the next stage of a process (3.4.1) or the next process.

Note 1 to entry: In English, in the context of software and documents (3.8.5), the word "release" is frequently used to refer to a version of the software or the document itself.

3.12.8 Rework

Action on a nonconforming (3.6.9) product (3.7.6) or service (3.7.7) to make it conform to the requirements (3.6.4).

Note 1 to entry: Rework can affect or change parts of the nonconforming product or service.

3.12.9 Repair

Action on a nonconforming (3.6.9) product (3.7.6) or service (3.7.7) to make it acceptable for the intended use.

Note 1 to entry: A successful repair of a nonconforming product or service does not necessarily make the product or service conform to the requirements (3.6.4). It can be that in conjunction with a repair a concession (3.12.5) is required.

Note 2 to entry: Repair includes remedial action taken on a previously conforming product or service to restore it for use, for example as part of maintenance.

Note 3 to entry: Repair can affect or change parts of the nonconforming product or service.

3.12.10 Scrap

Action on a nonconforming (3.6.9) product (3.7.6) or service (3.7.7) to preclude its originally intended use.

Example: Recycling, destruction.

Note 1 to entry: In a nonconforming service situation, use is precluded by discontinuing the service.

3.13 Terms Related to Audit

3.13.1 Audit

A systematic, independent and documented process (3.4.1) for obtaining objective evidence (3.8.3) and evaluating it objectively to determine the extent to which the audit criteria (3.13.7) are fulfilled.

Note 1 to entry: The fundamental elements of an audit include the determination (3.11.1) of the conformity (3.6.11) of an object (3.6.1) according to a procedure (3.4.5) carried out by personnel not being responsible for the object audited.

Note 2 to entry: An audit can be an internal audit (first party), or an external audit (second party or third party), and it can be a combined audit (3.13.2) or a joint audit (3.13.3).

Note 3 to entry: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organisation (3.2.1) itself for management (3.3.3) review (3.11.2) and other internal purposes and can form the basis for an organisation's declaration of conformity. Independence can be demonstrated by the freedom from responsibility for the activity being audited.

Note 4 to entry: External audits include those generally called second- and third-party audits. Second-party audits are conducted by parties having an interest in the organisation, such as customers (3.2.4), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organisations such as those providing certification/registration of conformity or governmental agencies.

Note 5 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition and Notes to entry have been modified to remove effect of circularity between audit criteria and audit evidence term entries, and Notes 3 and 4 to entry have been added.

3.13.2 Combined Audit

An audit (3.13.1) carried out together at a single auditee (3.13.12) on two or more management systems (3.5.3).

Note 1 to entry: The parts of a management system that can be involved in a combined audit can be identified by the relevant management system standards, product standards, service standards or process standards being applied by the organisation (3.2.1).

3.13.3 Joint Audit

An audit (3.13.1) carried out at a single auditee (3.13.12) by two or more auditing organisations (3.2.1).

3.13.4 Audit Programme

A set of one or more audits (3.13.1) planned for a specific time frame and directed towards a specific purpose.

[**Source:** ISO 19011:2011, 3.13, modified]

3.13.5 Audit Scope

The extent and boundaries of an audit (3.13.1).

Note 1 to entry: The audit scope generally includes a description of the physical locations, organisational units, activities and processes (3.4.1).

[**Source:** ISO 19011:2011, 3.14, modified – Note to entry has been modified]

3.13.6 Audit Plan

Description of the activities and arrangements for an audit (3.13.1).

[**Source:** ISO 19011:2011, 3.15]

3.13.7 Audit Criteria

A set of policies (3.5.8), procedures (3.4.5) or requirements (3.6.4) used as a reference against which objective evidence (3.8.3) is compared.

[**Source:** ISO 19011:2011, 3.2, modified – The term "audit evidence" has been replaced by "objective evidence"]

3.13.8 Audit Evidence

Records, statements of fact or other information, which are relevant to the audit criteria (3.13.7) and verifiable.

[**Source:** ISO 19011:2011, 3.3, modified – Note to entry has been deleted]

3.13.9 Audit Findings

Results of the evaluation of the collected audit evidence (3.13.8) against audit criteria (3.13.7).

Note 1 to entry: Audit findings indicate conformity (3.6.11) or nonconformity (3.6.9).

Note 2 to entry: Audit findings can lead to the identification of opportunities for improvement (3.3.1) or recording good practices.

Note 3 to entry: In English, if the audit criteria (3.13.7) are selected from statutory requirements (3.6.6) or regulatory requirements (3.6.7), the audit finding can be called compliance or non-compliance.

[**Source:** ISO 19011:2011, 3.4, modified – Note 3 to entry has been modified]

3.13.10 Audit Conclusion

Outcome of an audit (3.13.1), after consideration of the audit objectives and all audit findings (3.13.9).

[**Source:** ISO 19011:2011, 3.5]

3.13.11 Audit Client

Organisation (3.2.1) or person requesting an audit (3.13.1).

[**Source:** ISO 19011:2011, 3.6, modified – Note to entry has been deleted]

3.13.12 Auditee

The organisation (3.2.1) being audited.

[**Source:** ISO 19011:2011, 3.7]

3.13.13 Guide

A person appointed by the auditee (3.13.12) to assist the audit team (3.13.14).

[**Source:** ISO 19011:2011, 3.12]

3.13.14 Audit Team

One or more persons conducting an audit (3.13.1), supported if needed by technical experts (3.13.16).

Note 1 to entry: One auditor (3.13.15) of the audit team is appointed as the audit team leader.

Note 2 to entry: The audit team can include auditors-in-training.

[**Source:** ISO 19011:2011, 3.9, modified]

3.13.15 Auditor

A person who conducts an audit (3.13.1).

[**Source:** ISO 19011:2011, 3.8]

3.13.16 Technical Expert

A person who provides specific knowledge or expertise to the audit team (3.13.14).

Note 1 to entry: Specific knowledge or expertise relates to the organisation (3.2.1), the process (3.4.1) or activity to be audited, or language or culture.

Note 2 to entry: A technical expert does not act as an auditor (3.13.15) in the audit team (3.13.14).

[**Source:** ISO 19011:2011, 3.10, modified – Note 1 to entry has been modified]

3.13.17 Observer

A person who accompanies the audit team (3.13.14) but does not act as an auditor (3.13.15).

Note 1 to entry: An observer can be a member of the auditee (3.13.12), a regulator or other interested party (3.2.3) who witnesses the audit (3.13.1).

[**Source:** ISO 19011:2011, 3.11, modified – The verb "audit" has been removed from the definition. Note to entry has been modified]

Benefits of ISO 9001:2015

The potential benefits to an organisation of implementing a quality management system based on this International Standard are

- the ability to consistently provide products and services that meet customer and applicable
- statutory and regulatory requirements
- facilitating opportunities to enhance customer satisfaction
- addressing risks and opportunities associated with the context and objectives of the
- organisation
- the ability to demonstrate conformity to specified quality management system requirements
- integration with and alignment to an organisation's objectives
- greater involvement by top management to ensure motivation of employees towards goals
- and strategic objectives
- the value of different management systems "speaking the same language", making
- integration less difficult

Annexure B – Other International Standards On Quality Management and Quality Management Developed by ISO/TC 176

- ISO 9000 – Quality management systems – Fundamentals and vocabulary.
- ISO 9004 Managing for the sustained success of an organisation – A quality management
- approach.

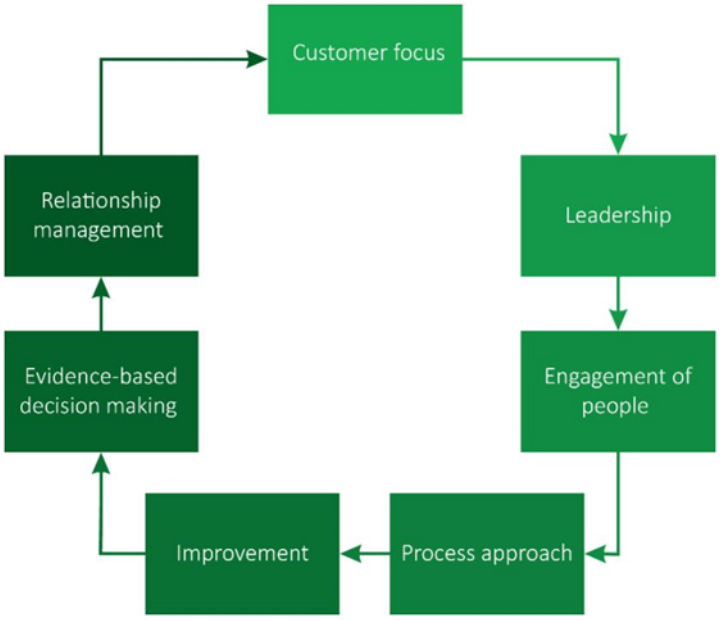
The International Standards outlined below can provide assistance to organisations when they are establishing or seeking to improve their quality management systems, their processes or their activities.

- ISO 10001 Quality management – Customer satisfaction – Guidelines for codes of conduct for
- organisations.
- ISO 10002 Quality management – Customer satisfaction – Guidelines for complaints handling
- in organisations.
- ISO 10003 Quality management – Customer satisfaction – Guidelines for dispute resolution
- external to organisations. ISO 10003 Quality management – Customer satisfaction – Guidelines for dispute resolution external to organisations
- ISO 10004 Quality management – Customer satisfaction – Guidelines for monitoring and
- measuring.

- ISO 10005 Quality management systems – Guidelines for quality plans.
- ISO 10006 Quality management systems – Guidelines for quality management in projects.
- ISO 10007 Quality management systems – Guidelines for configuration management.
- ISO 10008 Quality management – Customer satisfaction – Guidelines for business-to-
- consumer. Electronic commerce transactions.
- ISO 10012 Measurement management systems – Requirements for measurement processes and measuring equipment
- ISO/TR 10013 Guidelines for quality management system documentation.
- ISO 10014 Quality management – Guidelines for realising financial and economic benefits.
- ISO 10015 Quality management – Guidelines for training.
- ISO/TR 10017 Guidance on statistical techniques for ISO 9001:2000.
- ISO 10018 Quality management – Guidelines on people involvement and competence.
- ISO 10019 Guidelines for the selection of quality management system consultants and use of their services.
- ISO 19011 Guidelines for auditing management systems.

3 QUALITY MANAGEMENT

3.1 WHAT IS QUALITY?



Definition

Quality is the degree to which a set of inherent characteristics of an object fulfils requirements. "Inherent" means existing in the object, not assigned.

Quality Management Principles

1. Customer focus 2. Leadership

3. Engagement of people

4. Process approach

5. Improvement

6. Evidence-based decision-making

7. Relationship management

Clause 0.2 of the standard states the following:

"This International Standard is based on the quality management principles described in ISO 9000:2015."

The descriptions include:

- A **statement** of each principle
- A **rationale** of why the principle is important for the organisation

QMP 1 – Customer Focus

Statement

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

Rationale

- Sustained success is achieved when an organisation attracts and retains the confidence of
- customers and other interested parties.
- Every aspect of customer interaction provides an opportunity to create more value for the customer.
- Understanding current and future needs of customers and other interested parties contributes
- to sustain success of the organisation.

QMP 2 – Leadership

Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organisation's quality objectives.

Rationale

Creation of unity of purpose and the direction and engagement of people enable an organisation to align its strategies, policies, processes and resources to achieve its objectives.

QMP 3 – Engagement of People

Statement

Competent, empowered and engaged people at all levels throughout the organisation are essential to enhance the organisation's capability to create and deliver value.

Rationale

- In order to manage an organisation effectively and efficiently, it is important to respect and involve all people at all levels.
- Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organisation's quality objectives.

QMP 4 – Process Approach

Statement

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

Rationale

- The QMS consists of interrelated processes.
- Understanding how results are produced by this system enables an organisation to optimize the system and its performance.

QMP 5 – Improvement

Statement

Successful organisations have an ongoing focus on improvement.

Rationale

Improvement is essential for an organisation

- to maintain current levels of performance
- to react to changes in its internal and external conditions
- to create new opportunities

QMP 6 – Evidence-Based Decision-Making

Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

Rationale

- Decision-making can be a complex process and always involves some uncertainty.
- It often involves multiple types and sources of *inputs*, as well as their interpretation, which can be subjective.
- It is important to understand cause and effect relationships and potential unintended consequences.
- Facts, evidence and data analysis lead to greater objectivity and confidence in decisions made.

QMP 7 – Relationship Management

Statement

For sustained success, organisations manage their relationships with interested parties, such as providers.

Rationale

- Relevant interested parties influence the performance of an organisation.
- Sustained success is more likely to be achieved when the organisation manages relationships with all of its interested parties to optimise their impact on its performance. Relationship management with its provider and partner networks is often of particular importance.

4 UNDERSTANDING ISO 9001:2015

Clause 4 – Context of the Organisation

Applicable clauses

CLAUSE NO.	CLAUSE TITLE
4.1	Understanding the organisation and its context
4.2	Understanding the needs and expectations of Interested parties
4.3	Determining the scope of QMS
4.4	QMS and its processes

ISO 9001:2015 REQUIREMENTS –

4.1 CLAUSE 4 – CONTEXT OF THE ORGANISATION

Clause 4.1 – Understanding The Organisation and Its Context

What does it mean?

The organisation must ensure that:

- internal and external issues (factors) that affect its ability to achieve the intended results of
- the QMS will be taken into consideration when planning the QMS.
- the QMS is in line with the strategic objectives of the organisation.
- monitoring and review of external and internal issues is done.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 4.1

Clause 4.3 – (Managing for the sustained success of an organization) The organization's environment "An organization's environment will be undergoing change continually, regardless of its size (large or small), its activities and products, or its type (for profit or not-for-profit); consequently this should be monitored constantly by the organization. Such monitoring should enable the organization to identify, assess and manage the risks related to interested parties, and their changing needs and expectations.

Top management should make decisions for organizational change and innovation in a timely manner in order to maintain and improve the organization's performance."[12]

Clause 4.2 – Understanding The Needs and Expectations of Interested Parties

What does it mean?

The organisation must ensure:

- it identifies all interested parties' needs and expectations prior to developing the QMS
- that contractual agreements with specific deliverables that are required by clients, suppliers and/or contractors, are considered

- should the organisation choose to engage and agree to certain expectations from an external party, these expectations may become compliance obligations
- who the interested parties are:

INTERESTED PARTY	NEEDS AND EXPECTATIONS
Customers	Quality, price and delivery performance of products
Owners/shareholders	Sustained profitability and transparency
Employees	Good work environment, job security recognitions and reward
Suppliers and partners	Mutual benefits and continuity
Society	Environmental protection, ethical behaviour and compliance with statutory and regulatory requirements

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 4.2

Clause 4.4 - (Managing for the sustained success of an organisation) Interested parties, needs and expectations

"Interested parties are individuals and other entities that add value to the organisation, or are otherwise interested in, or affected by, the activities of the organisation. Meeting the needs and expectations of interested parties contributes to the achievement of sustained success by the organisation.

In addition, the needs and expectations of individual interested parties are different, can be in conflict with those of other interested parties, or can change very quickly. The means by which the needs and expectations of interested parties are expressed and met can take a wide variety of forms, including collaboration, co-operation, negotiation, outsourcing, or by terminating an activity.

Clause 4.3 – Determining The Scope of The QMS

What does it mean?

The organisation must ensure that:

- there is clarity around the physical and organisational boundaries as well as with products and services of the QMS.
- the QMS can be applicable to only a part or the whole of the organisation.
- should the organisation exclude requirements, it must ensure that they do not affects the
- ability or responsibility to ensure conformity of its products and services and enhancement of customer satisfaction.
- the documented scope to be made available to interested parties.

Clause 4.4 – QMS and Its Processes

Clause 4.4.1

What does it mean?

The organisation must ensure that:

- processes are identified and established, implemented, maintained and continually improved

- the inputs and outputs required to achieve the desired outcomes are defined
- the sequence and interactions of these processes are determined
- the criteria and methods to ensure effective operations, including how the organisation will monitor and measure the performance, will be determined
- resources required for these processes are determined and made available
- responsibilities are allocated for all defined processes
- risks and opportunities are addressed in accordance with Clause 6.1
- all processes are evaluated for effectiveness
- Where desired results are not achieved, changes are made to improve the processes

Clause 4.4.2

What does it mean?

The organisation must ensure that:

- documented information to support the operation of its processes are maintained
- documented information is retained in order to assure that processes are carried out as planned

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 4.4

Clause 4.1 - (Managing for the sustained success of an organization) General "To achieve sustained success, top management should adopt a quality management approach.
The organization's quality management system should be based on the principles described in Annex B. These principles describe concepts that are the foundation of an effective quality management system.

To achieve sustained success, top management should apply these principles to the organization's quality management system.

The organization should develop its quality management system to ensure:

- the efficient use of resources,
- decision-making based on factual evidence, and
- focus on customer satisfaction, as well as on the needs and expectations of other relevant interested parties.

Clause 7.1 - (Processes management) General

"Processes are specific to an organization and vary depending on the type, size and level of maturity of the organization. The activities within each process should be determined and adapted to the size and distinctive features of the organization.

The organization should ensure the proactive management of all processes, including outsourced processes, to ensure that they are effective and efficient, in order to achieve its objectives. This can be facilitated by adopting a "process approach" that includes establishing processes, interdependencies, constraints and shared resources.

Processes and their interrelationships should be reviewed on a regular basis and suitable actions should be taken for their improvement.

The processes should be managed as a system by creating and understanding the networks of processes, their sequences and interactions. The consistent operation of this system is often referred to as the "systems approach to management". The network can be described in a map of the processes and their interfaces.

Possible Challenges

- A high level/conceptual understanding of the internal and external issues needs to be identified.
- The requirements of external parties might have been overseen during the planning of the QMS and therefore not implemented in all areas of the organisation.

Task

Evaluate the following examples and discuss the differences between the possible context of the two types of organisations in Pictures 1 and 2.

Construction Industry Activities

Site cleaning in preparation for construction work, bore well digging, sump construction, foundation digging, carpenter work, wall construction, installation of extractor fans, electrical pipeline installations, plumbing work, plaster work, roof building.

Building an office building

Building a house

PICTURE 1	PICTURE 2
LIST DIFFERENCES BELOW	
Public safety	Fields of crops next to this site and possibility of wandering animals need to be considered
Lifting equipment and overhead cranes	There might be fresh water rivers in the area
Neighbouring companies or buildings may be affected by building activities	The noise of construction work might disturb the peace

4.2 CLAUSE 5 – LEADERSHIP

Applicable clauses

CLAUSE NO.	CLAUSE TITLE
5.1	Leadership and commitment
5.1.1	General
5.1.2	Customer focus
5.2	Quality policy (Title only)
5.2.1	Establishing the quality policy
5.2.2	Communicating the quality policy
5.3	Organisational roles, responsibilities and authorities

ISO 9001:2015 Requirements – Clause 5 – Leadership

Clause 5.1 Leadership and Commitment

Cause 5.1.1 – General

What does it mean?

Top management must ensure that:

- they demonstrate their involvement in the establishment, implementation and maintenance of the QMS
- the Quality policy and objectives are established and are aligned with the strategy of the organisation
- the QMS requirements are evident and integrated into the business processes and on all functional levels of the organisation
- the processes are implemented taking in consideration organisational risks, (as identified in Clause 6.1) and that a process-approach is followed
- they provide support to contribute to the effectiveness and improvement of the QMS

ISO 9004:2009 Linked Clauses

Clause 4.1 - (Managing for the sustained success of an organization) General See detail on page 41.

Clause 5.1.2 – Customer focus

What does it mean?

Top management must ensure that:

- they demonstrate commitment and leadership with respect to customer focus
- customer and applicable statutory and regulatory requirements are determined, (see Clause 8.2, Requirements for product and services), and are consistently met
- risks that might have a negative effect on conforming of products and services are identified opportunities to improve on customer requirements are defined and addressed
- customer satisfaction is consistently achieved and must be measured. (See Clause 9, Improvement)

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 5.1

Clause 4.4 - (Managing for the sustained success of an organization) Interested parties, needs and expectations See detail on page 40 (PM on page 40).

Clause 5.2 – Policy

Clause 5.2.1 – Establishing the quality policy

What does it mean?

Top management must ensure that the quality policy:

- is appropriate to the organisation's purpose and context
- supports the organisation's strategic direction
- provides a framework for quality objectives
- provides a commitment to achieve the applicable requirements
- includes a commitment to continually improvement of the QMS

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 5.2.1

Clause 5.1 - (Strategy and policy) General

"To achieve sustained success, top management should establish and maintain a mission, a vision and values for the organization. These should be clearly understood, accepted and supported by people in the organization and, as appropriate, by other interested parties.

NOTE: In this International Standard, a "mission" is a description of why the organization exists, and a "vision" describes its desired state, i.e. what the organization wants to be and how it wants to be seen by its interested parties."[16]

Clause 5.2 - (Strategy and policy) Strategy and policy formulation

"Top management should set out the organization's strategy and policies clearly, in order to get the mission, vision and values accepted and supported by its interested parties. The organization's environment should be regularly monitored to determine if there is a need to review and (when appropriate) revise the strategy

and policies. In order to establish, adopt and sustain an effective strategy and policy, the organization should have processes to:

- continually monitor and regularly analyse the organization's environment, including its customers' needs and expectations, the competitive situation, new technologies, political changes, economic forecasts, or sociological factors,
- identify and determine the needs and expectations of other interested parties,
- assess its current process capabilities and resources,
- identify future resource and technology needs,
- update its strategy and policies, and
- identify the outputs necessary to meet the needs and expectations of the interested parties.

These processes should be established in a timely manner, with any necessary plans and resources being provided to support them.

The formulation of an organization's strategy should also consider activities such as analyses of customer or regulatory demands, its products, its strengths, weaknesses, opportunities, and threats.
A defined process should exist for the formulation and review of the organisation's strategy."

Clause 5.2.2 – Communicating the quality policy

What does it mean?

The organisation must ensure that:

- the quality policy is documented and controlled as per Clause 7.5 (Documented information)
- the quality policy is communicated, understood and applied on all functional areas
- the quality policy is available to interested parties

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 5.2.2

Clause 5.4 - (Strategy and policy) Strategy and policy communication

"The effective communication of the strategy and policies is essential to the sustained success of the organization.

Such communication should be meaningful, timely and continual. Communication should also include a feedback mechanism, a review cycle and should incorporate provisions to proactively address changes in the organization's environment.

The organization's communication process should operate both vertically and horizontally and should be tailored to the differing needs of its recipients. For example, the same information can be conveyed differently to people within the organization than to customers or other interested parties."

Clause 5.3 – Roles, Responsibilities and Authorities

What does it mean?

Top management must ensure that:

- relevant roles and authorities are assigned and communicated in order to effectively control the QMS
- responsible person(s) are assigned to ensure conformance to the requirements of ISO 9001:2015
- persons are assigned to ensure that processes deliver their intended outputs

- persons are assigned to ensure performance of the QMS and opportunities for improvement are reported to them
- customer satisfaction always remains the focus of everybody in the organisation
- the integrity of the QMS is maintained when changes are planned and implemented

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 5.3

Clause 7.3 - (Processes management) Process responsibility and authority

"For each process, the organization should appoint a process manager (often referred to as the "process owner") with defined responsibilities and authorities to establish, maintain, control and improve the process and its interaction with other processes. The process manager could be a person or a team, depending on the nature of the process and the organization's culture.

The organization should ensure that the responsibilities, authorities and roles of process managers are recognized throughout the organization, and that the people associated with the individual processes have the competences needed for the tasks and activities involved."

Possible Challenges

- Top management must spend more time involved in the QMS decision-making processes.
- Establishment and effectiveness of the QMS system will now be top management's accountability.
- Often organisations do not effectively communicate the quality policy to all functional areas.
- Top management's involvement must be more clearly defined in contractual agreements and job descriptions.
- Specific QMS responsibilities must be allocated to line managers. Job descriptions must be changed to include this responsibility.
- Management representatives for the QMS do not have to be removed from their positions, but in some organisations, this might occur.
- Knowledge of QMS principles must be improved.

4.3 CLAUSE 6 – PLANNING

Applicable clauses

CLAUSE NO.	CLAUSE TITLE
6.1	Actions to address risks and opportunities
6.2	Quality objectives and planning to achieve them
6.3	Planning of changes

ISO 9001:2015 Requirements – Clause 6 – Planning

Clause 6.1 – Actions to Address Risks and Opportunities

Clause 6.1.1

What does it mean?

- When planning the QMS consider the context of the organisation and needs and expectations of interested parties as defined in Clause 4.1 and 4.2.
- Risks and opportunities must be defined to assure that the intended results are achieved.
- Risks and opportunities need to be addressed for the prevention and reduction of deviations/undesired effects.
- The achievement of continual improvement and enhancement of desirable effects must be the outcome of addressing the risks and opportunities.

Clause 6.1.2

What does this mean?

The organisation must ensure that:

- actions to address risks and opportunities are planned
- the actions planned are integrated in all appropriate functional areas of the organisation to improve the QMS processes
- actions implemented are evaluated for effectiveness
- actions are proportionate to the impact on the conformity to products and services

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 6.1

Clause 7.2 - (Processes management) Process planning and control

"The organization should determine and plan its processes and define the functions that are necessary for providing products that can continue to meet the needs and expectations of customers and other interested parties, on an ongoing basis. Processes should be planned and controlled to be in accordance with the organization's strategy and should address management activities, provision of resources, product realization, monitoring, measurement and reviewing activities.

In the planning and control of processes, consideration should be given to:

- analyses of the organization's environment,
- short- and long-term forecasts of market developments,
- the needs and expectations of the interested parties,
- objectives to be achieved,
- statutory and regulatory requirements,
- potential financial and other risks,
- process inputs and outputs,
- interactions with other processes,
- resources and information,

- activities and methods,
- records that are required or desired,
- measurement, monitoring and analysis,
- corrective and preventive actions, and
- improvement and/or innovation activities.

Process planning should include consideration of the determined needs for the organization to develop or acquire new technologies, or develop new products or product features, for added value.

Clause 9.1 - (Improvement, innovation and learning) General

"Depending on the organization's environment, improvement (of its current products, processes, etc.) and innovation (to develop new products, processes, etc.) could be necessary for sustained success.

Learning provides the basis for effective and efficient improvement and innovation.

Improvement, innovation and learning can be applied to:

- products,
- processes and their interfaces,
- organizational structures,
- management systems,
- human aspects and culture,
- infrastructure, work environment and technology, and
- relations with relevant interested parties.

Fundamental to effective and efficient improvement, innovation and learning is the ability and enablement of the people in the organization to make informed judgments on the basis of data analyses and the incorporation of lessons learned.

Clause 9.2 - (Improvement, innovation and learning) Improvement

"Improvement activities can range from small-step continual improvements at a workplace to significant improvements of the entire organization.

The organization should define objectives for the improvement of its products, processes, organizational structures and its management system through the analysis of data.

The improvement processes should follow a structured approach, such as the "Plan-Do-Check-Act" (PDCA) methodology. The methodology should be applied, consistently with the process approach, for all processes.

The organization should ensure that continual improvement becomes established as a part of the organizational culture by:

- providing the opportunities for people in the organization to participate in improvement activities, through their empowerment,
- providing the necessary resources,

- establishing recognition and reward systems for improvement, and
- continual improvement of the effectiveness and efficiency of the improvement process itself.

Clause 9.3.5 - (Innovation) Risks

"The organization should assess the risks related to planned innovation activities, including giving consideration to the potential impact on the organization of changes, and prepare preventive actions to mitigate those risks, including contingency plans, where necessary.

Clause 6.2 Quality Objectives and Planning to Achieve Them

Clause 6.2.1

What does this mean?

The organisation must ensure the following:

- that quality objectives are set on various functional levels and processes.
- that objectives are:

o consistent with the QMS

o measurable

o consistent with requirements

o relevant to conformity of products and services

o focused on customer satisfaction

o monitored

o communicated

o documented

Clause 6.2.2

What does this mean?

The organisation must ensure that it defines:

- WHAT will be done
- What RESOURCES will be required
- WHO will be responsible
- WHEN will objectives be completed
- HOW results will be evaluated

Always ensure that QUALITY OBJECTIVES are S.M.A.R.T (Specific, Measurable, Achievable, Realistic, Timely).

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 6.2

None.

Clause 6.3 Planning of Changes

What does this mean?

The organisation must ensure the following:

- Where changes to the QMS are identified, the changes shall be carried out in a planned manner. Refer to Clause 4.4.
- That the purpose of the changes is considered.
- The potential consequences will be considered.
- The integrity of the QMS will be considered.
- The availability of resources will be considered.
- That the allocation or reallocation of responsibilities and authorities are considered

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 6.3

None.

Possible Challenges

- Risks and opportunities for external parties must be defined and the extent of control must be defined.
- Risks are not always actioned appropriately to the extent of negative impact on product and
- service delivery.

REMEMBER: The risk-based approach is everybody's responsibility.

- Objectives are often not met within the planned timeframes.
- Sufficient resources are not available to complete objectives.
- Objectives are not always aligned with strategic objectives or properly communicated.
- It often happens that the organisation makes changes in processes and the QMS is not reviewed and updated. This results in a reduction in the integrity of the QMS and the ineffectiveness of the QMS and its processes.

Examples

QUALITY IMPACTS			
IMPACT	**COST**	**TIME**	**QUALITY**
VERY LOW (1)	Manageable by	Slight slippage against internal targets	Slight reduction in quality/ scope, no overall

	exchange against internal budgets		impact
LOW (2)	Requires some additional funding from institution	Slight slippage against key milestones or published targets	Failure to include certain "nice to have" elements
MEDIUM (3)	Requires significant additional funding from institution	Delay affects key stakeholders – loss of confidence in the project	Significant elements of scope for functionality will be unavailable
HIGH (4)	Requires significant reallocation of institutional funds (or Lending)	Failure to meet key deadlines in relation to the academic year or strategic plan	Failure to meet the needs of a large proportion of stakeholders
VERY HIGH (5)	Increase threatens viability of project	Delay jeopardies viability of project	Project outcomes effectively unusable

Figure 6: Example quality impact matrix for a risk assessment

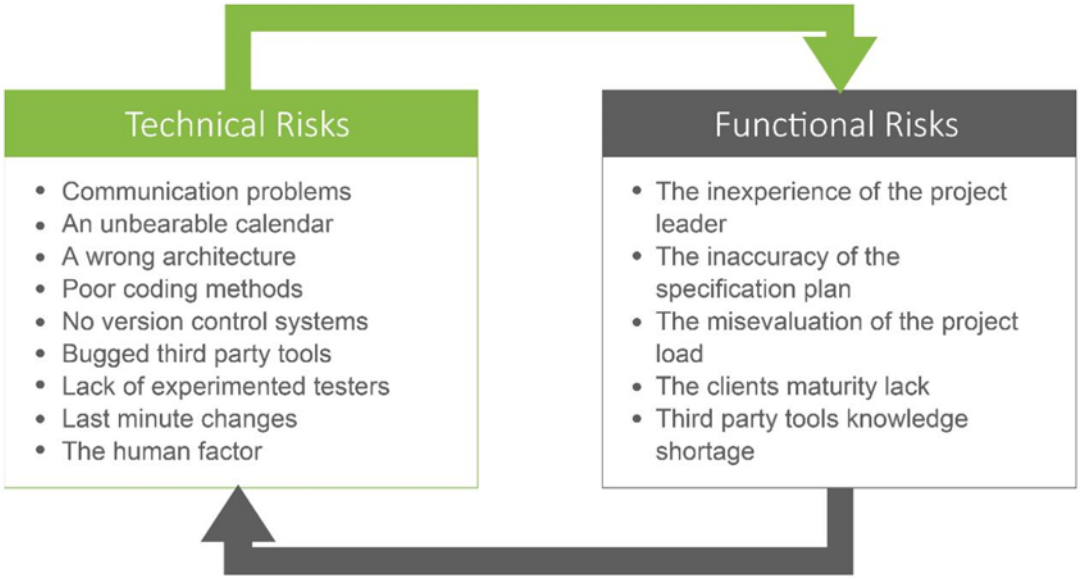


Figure 7: Example quality impact matrix for a risk assessment

4.4 CLAUSE 7 – SUPPORT

Applicable clauses

CLAUSE NO.	CLAUSE DESCRIPTION
7.1	Resources (Title only)
7.1.1	General
7.1.2	People

7.1.3 Infrastructure

7.1.4 Environment for the operation of processes

7.1.5 Monitoring and measuring resources (Title only)

7.1.5.1 General

7.1.5.2 Measurement traceability

7.1.6 Organisational knowledge

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented Information (Title only)

7.5.1 General

7.5.2 Creating and updating documents

7.5.3 Control of documented information

ISO 9001:2015 Requirements – Clause 7 – Support

CLAUSE 7.1 – RESOURCES

Clause 7.1.1 General

What does this mean?

The organisation must ensure that:

- resources are determined to establish, implement, maintain and continually improve the QMS
- the capabilities of existing internal resources are considered
- the constraints on existing internal resources are considered
- the needs of external providers are considered

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.1.1

Clause 6.1 - (Resource management) General

"The organization should identify the internal and external resources that are needed for the achievement of the organization's objectives in the short and long term. The organization's policies and methods for resource management should be consistent with its strategy.

To ensure that resources (such as equipment, facilities, materials, energy, knowledge, finance and people) are used effectively and efficiently, it is necessary to have processes in place to provide, allocate, monitor, evaluate, optimize, maintain and protect those resources.

To ensure the availability of the resources for future activities, the organization should identify and assess the risks of potential scarcity, and continually monitor current use of resources to find opportunities for improvement of their use. In parallel, research for new resources, optimized processes and new technologies should take place.

The organization should periodically review the availability and suitability of the identified resources, including outsourced resources, and take action as necessary. The results of these reviews should also be used as inputs into the organization's reviews of its strategy, objectives and plans.

Clause 7.1.2 – People

What does this mean?

The organisation must ensure that:

- it determines and provides persons that can effectively implement and control the QMS and its processes.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.1.2

Clause 6.3.1 - (People in the organisation) Management of people

"People are a significant resource of an organization and their full involvement enhances their ability to create value for interested parties. Top management should, through its leadership, create and maintain a shared vision, shared values and an internal environment in which people can become fully involved in achieving the organization's objectives.

As people are a most valuable and critical resource, it is necessary to ensure that their work environment encourages personal growth, learning, knowledge transfer and teamwork. People management should be performed through a planned, transparent, ethical and socially responsible approach. The organization should ensure that the people understand the importance of their contribution and roles.

The organization should establish processes that empower people to – translate the organization's strategic and process objectives into individual job objectives, and to establish plans for their achievement,

- identify constraints to their performance,
- take ownership and responsibility to solve problems,
- assess personal performance against individual job objectives,
- actively seek opportunities to enhance their competence and experience,
- promote teamwork and encourage synergy between people, and
- share information, knowledge and experience within the organization." [25]

Clause 7.1.3 – Infrastructure

What does this mean?

The organisation must ensure that:

- it provides and maintains the infrastructure so that processes can be effectively implemented.

NOTE: Infrastructure can include:

- buildings and associated utilities
- equipment, including hardware and software
- transportation resources
- information and communication technology

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.1.3

Clause 6.5 - (People in the organization) Infrastructure

"The organization should plan, provide and manage its infrastructure effectively and efficiently. It should periodically assess the suitability of the infrastructure to meet organizational objectives. Appropriate consideration should be given to:

- the dependability of the infrastructure (including consideration of availability, reliability,

maintainability, and maintenance support)

- safety and security

- infrastructure elements related to products and processes

- the efficiency, cost, capacity and work environment

- the impact of the infrastructure on the work environment

The organization should identify and assess the risks associated with the infrastructure and take action to mitigate the risks, including the establishment of adequate contingency plans.

Clause 7.1.4 – Environment for the operation of processes

What does this mean?

The organisation must ensure that:

- the environment where a specific process or activity is executed, is suitable to achieve the desired outcomes.

A "suitable environment" can be a combination of human and physical factors, for example,

- social, (for example, non-discriminatory, calm, non-confrontational)

- psychological (for example, stress reducing, burnout prevention, emotionally protective)
- physical (for example, temperature, heat, humidity, light, airflow, hygiene, noise)

These factors can differ substantially depending on the products and services provided. It is required by the OHS Act No.85 of 1993 Section 8 that safety hazards in the workplace be identified and that reasonable steps be taken to ensure that those hazards are eliminated or mitigated.

The National Environmental Management Act No. 107 of 1998 and its Environmental Impact Assessment Regulations (GN982 of 2014) require an organisation to conduct an Environmental Impact Assessment to indicate whether the operations of the organisation have an impact on the environment where people are working.

This needs to be considered under the requirements of Clause 4.2 (Understanding the needs and expectations of interested parties), Clause 5.1.2 (Customer focus), Clause 8.2.2 (Determining the requirements for products and services), Clause 8.2.3 (Review of the requirements for products and services), Clause 8.3.3 (Design and development inputs), Clause 8.4.2 (Type and extent of control), Clause 8.5.5 (Post-delivery activities).

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.1.4

Clause 6.6 - (People in the organization) Work environment

"The organization should provide and manage a suitable work environment to achieve and maintain the sustained success of the organization and the competitiveness of its products. A suitable work environment, as a combination of human and physical factors, should include consideration of:

- creative work methods and opportunities for greater involvement to realize the potential of people in the organization,
- safety rules and guidance and the use of protective equipment, ergonomics,
- psychological factors, including workload and stress, workplace location,
- facilities for people in the organization,
- maximization of efficiency and minimization of waste,
- heat, humidity, light, airflow, and
- hygiene, cleanliness, noise, vibration and pollution.

The work environment should encourage productivity, creativity and well-being for the people who are working in or visiting the organization's premises (e.g. customers, suppliers, and partners). At the same time, the organization should ensure that its work environment complies with applicable statutory and regulatory requirements and addresses applicable standards (such as those for environmental and occupational health and safety management).

Clause 7.1.5 Monitoring and measuring resources

Clause 7.1.5.1 – General

What does this mean?

The organisation must ensure that sufficient resources are available to:

- provide valid and reliable results of products and service monitoring and measuring.

The organisation must ensure that resources provided are:

- suitable for the specific monitoring and measurement activities that are being undertaken
- maintained to ensure their continuing fitness for their purpose

It is imperative that the organisation retains documented information as evidence that resources are fit for the purpose of monitoring and measuring activities

Clause 7.1.5.2 – Measurement traceability

What does this mean?

The organisation must ensure that:

- products and services are traceable during the production process to ensure that verification and validation during the monitoring and measurement activities are dependable
- where calibrated or verified equipment is used where international or national measurement standards are not available, documented information is retained to show the basis used
- where measuring equipment is used, they will be identified in order to show calibration status - where measuring equipment is used, they will be safeguarded from adjustments, damage or deterioration that can influence the validity of the measurement results

- where it was determined that the measurement results were deviating from the expected results, actions must be taken to ensure that verification and validation results are correct when it is determined that measuring equipment is found to be unfit for its intended purpose

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.1.5

Clause 8.1 - (Monitoring, measurement, analysis and review) General

"To achieve sustained success in an ever-changing and uncertain environment, it is necessary for the organisation to regularly monitor, measure, analyse and review its performance.

Clause 7.1.6 – Organisational knowledge

What does this mean?

The organisation must ensure that:

- knowledge that is necessary for the operation of its processes is identified
- it maintains the internal knowledge and makes it available to the extent required. This means that the organisation must focus on retention of knowledge and experienced workers to reduce costs and improve efficiency of the QMS
- where needs and trends change, the need for training and updated or additional knowledge is assessed

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.1.6

Clause 6.7.1 - (Knowledge, information and technology) General

"The organization should establish and maintain processes to manage knowledge, information and technology as essential resources. The processes should address how to identify, obtain, maintain, protect, use and evaluate the need for these resources. The organization should share such knowledge, information and technology with its interested parties, as appropriate.

Clause 6.7.2 - (Knowledge, information and technology) Knowledge

"Top management should assess how the organization's current knowledge base is identified and protected. Top management should also consider how to obtain the knowledge required to meet the present and future needs of the organization from internal and external sources, such as academic and professional institutions.

There are many issues to consider when defining how to identify, maintain and protect knowledge, such as:

- learning from failures, near miss situations and successes,
- capturing the knowledge and experience of people in the organization,
- gathering knowledge from customers, suppliers and partners,
- capturing undocumented knowledge (tacit and explicit) that exists within the organization,
- ensuring the effective communication of important information content (particularly at each
- interface in the supply and production chains), and
- managing data and records."

Clause 6.7.3 - (Knowledge, information and technology) Information

"The organization should establish and maintain processes to gather reliable and useful data and for converting such data into the information necessary for decision-making.

This includes the processes needed for the storage, security, protection, communication and distribution of data and information to all relevant parties. The organization's information and communication systems need to be robust and accessible, to ensure their capabilities. The organization should ensure the integrity, confidentiality and availability of information relating to its performance, process improvements, and on progress towards the achievement of sustained success.

Clause 7.2 – Competence

What does this mean?

The organisation must ensure that:

- it determines the competency level of person(s) doing work under its control. This can be done during performance discussions, on-the-job-observations and presented in the format of a training matrix
- that competency can be verified through appropriate education, training or experience information. This can be done with evidence of training certificates, attendance registers, professional registrations, etc.
- where it is required for people to improve/obtain competency, actions will be taken and these actions will be evaluated for effectiveness. This mean that when workers attend training, the organisation must ensure that the application of knowledge is evaluated afterwards.

NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.2
Clause 6.3.1 - (People in the organization) Management of people
See detail on page 54 (PM on page 53).

Clause 6.3.2 - (People in the organization) Competence of people

"In order to ensure that it has the necessary competences, the organization should establish and maintain a "people development plan" and associated processes; these should assist the organization in identifying, developing and improving the competence of its people through the following steps

- identifying the professional and personal competences the organization could need in the short and long term, in accordance with its mission, vision, strategy, policies, and objectives,
- identifying the competences currently available in the organization and the gaps between what is available and what is currently needed and could be needed in the future,
- implementing actions to improve and/or acquire competences to close the gaps,
- reviewing and evaluating the effectiveness of actions taken to ensure that the necessary competences have been acquired, and
- maintaining competences that have been acquired.

Clause 7.3 – Awareness

What does this mean?

The organisation must ensure that:

- the following documented information is communicated via awareness sessions to all persons working under the control of the organisation:

o the quality policy

o relevant quality objectives

o the contribution that they have towards the effectiveness of the QMS

o the benefits of improved performance of the QMS

o the consequences/implications of not complying with the QMS requirements

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.3

None.

Clause 7.4 – Communication

What does this mean?

The organisation must ensure that:

- a communication process is established, implemented and maintained
- communication is consistent and reliable
- communication received about the QMS, is responded to
- information that was communicated is documented
- determination of the relevant communication includes:

o what will be communicated (refer to "What must be communicated" below)

o who will communicate (who will transfer the information?)

o when information will be communicated

o with whom will be communicated (applies to contractors, as well as sub-contractors)

o how the organisation will communicate (for example, emails, communication boards, SMSs, etc.)

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.4

Clause 5.4 - (Strategy and policy) Strategy and policy communication

See detail on page 46 (PM on page 45).

Clause 7.5 – Documented Information

ISO 9001:2015, Annexure A

A.6 Documented information

"As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5).

Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organisation is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organisation might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organisation shall monitor and review the information about these external and internal issues"), there is no requirement that this information is to be documented. In such situations, the organisation can decide whether or not it is necessary or appropriate to maintain documented information.

Clause 7.5.1 – General

What does this mean?

The organisation must ensure that:

- QMS includes documented information to ensure a suitable, adequate and effective QMS, including those of external origin
- a focus on implementation of QMS not a complex document control system
- QMS includes documentation required by the standard does not have to be in the form of a manual, for example, flow charts

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.5.1

Clause 6.7.3 - (Knowledge, information and technology) Information

"The organization should establish and maintain processes to gather reliable and useful data and for converting such data into the information necessary for decision-making.

This includes the processes needed for the storage, security, protection, communication and distribution of data and information to all relevant parties. The organization's information and communication systems need to be robust and accessible, to ensure their capabilities. The organization should ensure the integrity, confidentiality and availability of information relating to its performance, process improvements, and on progress towards the achievement of sustained success.

Clause 7.5.2 – Creating and updating documented information

What does this mean?

The organisation must ensure that:

- the type(s) of documentation required to control the organisation's processes are identified
- the level of language is appropriate to the audience

- the format and media in which information is presented is effective for the transfer of information
- documented information is reviewed and approved for suitability and adequacy

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.5.2

None.

Clause 7.5.3 – Control of documented information

Clause 7.5.3.1

What does this mean?

The organisation must ensure that documented information:

- is controlled in a way that it is suitable and available at the time that it is needed
- is adequately protected from loss of confidentiality, improper use, or loss of integrity

Clause 7.5.3.2

What does this mean?

The organisation must ensure that the following documented information activities are controlled:

- the distribution of documented information
- the accessibility of documented information
- the retrieval of documented information
- the proper and intended use of documented information
- the storage and preservation of documents
- version control of documents
- retention and disposition of documents
- documentation of external origin of documents

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 7.5.3

None.

Possible Challenges

Resources

- Insufficient, inadequate and/or incompetent staff establish, implement and maintain the QMS.
- It may be a challenge to find employees that understand the integration of the QMS completely.
- Financial resources might be a challenge to maintain the QMS effectively.
- Often technology is not taken into consideration and therefore a manual system, instead of electronic management, is utilised to manage and control the QMS.

Competency

- Internal training is often conducted by people not competent as assessors.
- Non-accredited training is often provided which provides room for ineffective training to be conducted.
- The measurement of the effectiveness of training is not done by training providers.
- Records of training are often not maintained.

Awareness

- There is often no time allocated to conduct awareness sessions.
- Awareness sessions are often not conducted on an acceptable level of understanding or in an understandable language.
- Records of awareness sessions is often not kept.
- Understanding of the content is often not measured through an assessment or on-job- observations.

Communication

It is often noted that communication is not addressed on ALL levels of the organisation and the method and language of information shared is not suitable for the literacy level of the audience receiving the information.

Examples

Examples of Resources

- Manpower – employees, contractors, suppliers, any person that can deliver the required actions to maintain the QMS
- Money – budget to appoint people, put necessary controls in place to reduce environmental and occupational health and safety risks and address opportunities for improvement(s)
- Machinery – maintenance of machinery, calibrations, purchasing of equipment and machinery
- Methods – procedures, work instructions, processes, standards, etc.
- Materials – raw materials for production/manufacturing purposes, ingredients, etc.

Examples of Competency Documents

- Training matrix
- Training attendance registers
- Competency certificates, etc.

Examples of Awareness Documents

- Attendance registers of toolbox talks with contractors, subcontractors, employees in relation to quality risks for processes in their relevant work area.
- Awareness posters with relevant content of the QMS on notice boards.
- The displaying of the organisation's QMS policy

Examples of Communication Documents

- Formal – documented meeting minutes, drawings, procedures, memos, safety signage etc.
- Informal – awareness posters, toolbox talks (if not documented), brainstorming sessions.
- Unofficial – office discussions with a team.

Examples of Management System Document

- Operating procedures cold chain control and shelf-life guidelines
- Client requirements or agreements
- Order forms
- Delivery notes
- Inspection checklists
- Drawings of construction work
- Process flows
- QMS policy
- Documented QMS objectives
- Legal register
- Legal compliance reports
- Competency certificates
- Training and awareness attendance registers
- Training content
- Aspects and impacts assessments
- Risk assessments • Job descriptions
- Company organograms
- SHE organograms
- Legal appointment letters
- Inspection forms
- Audit tools
- Audit reports
- Meeting minutes
- Calibration certificates
- Safety signage
- Non-conformance reports
- Corrective action reports
- Financial documents

The Purpose of Documents

Figure 8: Purpose of documents

4.5 CLAUSE 8 – OPERATION

Applicable clauses

CLAUSE NO.	CLAUSE DESCRIPTION
8.1	Operational planning and control
8.2	Requirements for products and services (Title only)
8.2.1	Customer communication
8.2.2	Determining the requirements for products and services
8.2.3	Review of the requirements for products and services
8.2.4	Changes to requirements for products and services
8.3	Design and development of products and services (Title only)
8.3.1	General
8.3.2	Design and development planning
8.3.3	Design and development inputs
8.3.4	Design and development controls
8.3.5	Design and development outputs
8.3.6	Design and development changes
8.4	Control of externally provided processes, products and services (Title only)
8.4.1	General
8.4.2	Type and extent of control
8.4.3	Information for external providers
8.5	Production and service provision (Title only)
8.5.1	Control of production and service provision
8.5.2	Identification and traceability
8.5.3	Property belonging to customers or external providers
8.5.4	Preservation
8.5.5	Post-delivery activities
8.5.6	Control of changes
8.6	Release of products and services
8.7	Control of nonconforming outputs

Definition of Operations:

"Operations management is an area of management concerned with overseeing, designing, and controlling the process of production and redesigning business operations in the production of goods or services."

ISO 9001:2015 Requirements – Clause 8 – Operation

Clause 8.1 - Operational Planning and Control Requirements

What does this mean?

The organisation must ensure that:

- processes are established, implemented and controlled as defined in Clause 4.4 (QMS and its processes)
- these processes address the requirements of products and services
- that actions identified in Clause 6 (actions to address risks and opportunities) are planned, implemented and controlled
- criteria for all processes are established to achieve the desired results for products and services; these criteria must include when products and services can be accepted or not
- sufficient resources (as defined in Clause 7.1), are available to conform to product and service requirements
- control of the process is implemented in accordance to the criteria identified
- documented information is determined, maintained and retained to the extent to assure processes were carried out as planned and demonstrate the conformity of products and services to their requirements
- when there is change in operational processes, these changes are controlled in order to reduce any adverse effects on the business and where changes are unplanned, the consequences will be reviewed and actioned to mitigate any adverse effects
- any processes that are outsourced are controlled

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.1

Clause 7.2 - (Processes management) Process planning and control

See detail on page 48 (PM o page 47).

Clause 8.2 Requirements for Products and Services

Clause 8.2.1 – Customer communication

What does this mean?

The organisation must ensure that:

- customers are informed about information related to products and services, for example, the purpose of the product, how it should be used, who can use it, what is the content of it and what the customer can expect from the product
- queries from customers are handled, for example, orders, requests for change or other information
- feedback from customers is obtained to ensure customer satisfaction or complaints
- customer property is controlled and protected and customer informed of how this is done
- customers are informed of specific requirements for contingency actions when relevant

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.2.1

Clause 5.4 - (Strategy and policy) Strategy and policy communication

See detail on page 46 (PM on page 45).

Clause 8.2.2 – Determining the requirements for products and services

What does this mean?

The organisation must ensure that:

- requirements for products and services are defined to include:

o statutory and regulatory requirements
o those required by the organisation

- it can meet the claims it makes regarding products and services

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.2.2

None.

Clause 8.2.3 – Review of the requirements for products and services

Clause 8.2.3.1

What does this mean?

The organisation must ensure that:

- it has the ability to meet the specific requirements as defined in Clause 8.2.2
- it conducts a review before committing to supply the products and services taking in

consideration:

- the delivery and post-delivery activities required, for example, transportation of products, when a product can be activated or used
- requirements not stated by the customer but required by a manufacturer, for example, a cell phone that needs to be charged before it is used
- requirements specified by the organisation to ensure a high standard of quality product or service delivery, for example, if you manufacture ear pieces and a component must be imported and the

organisation does not have control over these processes, it has to take the uncertainty of time of delivery into consideration

- statutory and regulatory requirements as stated in Clause 8.2.2
- contract or order requirements that differs from those previously expressed. This must be resolved during the activities explained in Clause 8.2.1 (customer communication)
- all customer requirements are confirmed and documented before acceptance of the order where the customer does not provide a documented statement of requirements

NOTE: Where confirmation of requirements is impractical, advertising or product information catalogues can be used.

Clause 8.2.3.2

What does this mean?

The organisation must ensure that:

- documented information is kept to proof that the organisation reviewed the requirements and where any new requirements for products and services were determined.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.2.3

None.

Clause 8.2.4 – Changes to requirements for products and services

What does this mean?

The organisation must ensure that:

- when requirements for products and services change, documented information is amended and communicated.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.2.4

None.

Clause 8.3 – Design and Development of Products and Services

Clause 8.3.1 – General

What does this mean?

The organisation must ensure that:

- a design and development process is established, implemented and maintained
- the process indicates how the products and services will be provided

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.3.1

Clause 9.3 - (Improvement, innovation and learning) Innovation

Clause 9.3.1 - General

"Changes in the organization's environment could require innovation in order to meet the needs and expectations of interested parties. The organization should:

- identify the need for innovation,
- establish and maintain an effective and efficient innovation process, and
- provide the related resources.

Clause 9.3.2 - Application

"Innovation can be applied to issues at all levels, through changes in:

- technology or product (i.e. innovations that not only respond to the changing needs and expectations of customers or other interested parties, but also to anticipate potential changes in the organization's environment and product lifecycles),
- processes (i.e. innovation in the methods for product realization, or innovation to improve process stability and reduce variance),
- the organization (i.e. innovation in its constitution and organizational structures), and
- the organization's management system (i.e. to ensure that competitive advantage is maintained and new opportunities are utilized, when there are emerging changes in the organization's environment).

Clause 9.3.3 - Timing

"The timing for the introduction of an innovation is usually a balance between the urgency with which it is needed versus the resources that are made available for its development. The organization should use a process that is in alignment with its strategy to plan and prioritize innovations. The organization should support the innovation initiatives with the resources needed.

Clause 9.3.4 - Process

"The establishment, maintenance and management of processes for innovation within the organization can be influenced by:

- the urgency of the need for innovation,
- innovation objectives and their impact on products, processes and the organizational structures,
- the organization's commitment to innovation,
- people's willingness to challenge and change the status quo, and
- the availability or emergence of new technologies.

Clause 8.3.2 – Design and development planning

What does this mean?

This clause refers to how the organisation plans to produce or supply the products and services requested by the customer. The following must be considered:

- the nature, duration and complexity of the design and development activities
- the process stages, including reviews
- the required design and development verification and validation activities
- the responsibilities and authorities involved in the design and development process
- the internal and external resource needs for the design and development of products and services
- the need to control interfaces between persons involved in the design and development process

- the need for involvement of customers and users in the design and development process
- the requirements for subsequent provision of products and services
- the level of control expected for the design and development process by customers and other relevant interested parties
- the documented information needed to demonstrate that design and development requirements have been met

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.3.2

None.

Clause 8.3.3 – Design and development inputs

What does this mean?

The following design and development requirements must be determined:

- functionality
- performance
- information derived from previous similar activities
- legal
- standards or codes of practice that the organisation has committed to implement
- consequences of failure

Inputs must be adequate, complete and unambiguous where conflicting inputs must be resolved and documented information must be retained

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.3.3

None.

Clause 8.3.4 – Design and development controls

What does this mean?

Controls for design and development process must include:

- definition of results to be achieved
- reviews to evaluate if requirements can be met
- verification to ensure outputs meet input requirements
- validation to ensure product or service meets requirements for application or intended use
- assurance that actions will be taken if any issues are determined during reviews, verification or validation
- retention of documented information of activities

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.3.4

None.

Clause 8.3.5 – Design and development outputs

What does this mean?

Outputs of design and development must:

- meet input requirements
- be adequate for processes for the provision of products and services
- include or reference monitoring and measuring requirements (as appropriate), including acceptance criteria
- specify characteristics that are essential for intended purpose and the safe and proper provision of products and services
- be retained as documented information

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.3.5

None.

Clause 8.3.6 – Design and development changes

What does this mean?

Changes made during or after the design and development of products and services must be identified, reviewed and controlled. Documented information of the following must be retained:

- changes
- results of reviews
- authorisation of changes
- actions taken to prevent adverse impacts

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.3.6

None

Clause 8.4 – Control of Externally Provided Processes, Products and Services

Clause 8.4.1 - General

What does this mean?

The organisation must ensure the following:

- that externally provided processes, for example, transportation, supplier of goods and materials, comply with the requirements for products and services

- that externally provided processes, products and services be controlled when:

o they are intended for incorporation into the organisation's own products and services

o they are provided directly to the customer by the provider on behalf of the organisation

o the organisation decided for an external provider to provide a process or part of a process

- criteria for the following must be determined and applied for external providers:

o evaluation

o selection

o monitoring of performance

o re-evaluation

- documented information of the activities above and any actions arising from evaluations are retained

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.4.1

Clause 6.4.1 - (Suppliers and partners) General

"Partners can be suppliers of products, service providers, technological and financial institutions, governmental and non-governmental organizations or other interested parties. Partners can contribute with any type of resource, as agreed and defined in a partnership agreement.

The organization and its partners are interdependent and a mutually beneficial relationship enhances their capabilities to create value. The organization should consider partnership as a specific form of relationship with suppliers, where suppliers can invest in and share the profits or losses of the organization's area of activity.

When an organization is developing partnerships, the organization should give consideration to issues such as:

- the provision of information to partners, as appropriate, to maximize their contributions,
- supporting partners, in terms of providing them with resources (such as information, knowledge, expertise, technology, processes, and shared training),
- the sharing of profits and losses with partners, and
- improving the performance of partners.

Clause 6.4.2 - (Suppliers and partners) Selection, evaluation and improvement of the capabilities of suppliers and partners

"The organization should establish and maintain processes to identify, select, and evaluate its suppliers and partners, in order to continually improve their capabilities and to ensure that the products or other resources they provide meet the needs and expectations of the organization.

In selecting and evaluating suppliers and partners, the organization should consider issues such as:

- their contribution to the organization's activities and ability to create value for the
- organization and its interested parties,
- the potential for continually improving their capabilities,
- the enhancement of its own capabilities that can be achieved through co-operation with
- the suppliers and partners, and
- the risks associated in the relationships with the suppliers and partners.

Together with its suppliers and partners, the organization should seek to continually improve the quality, price and delivery of products provided by the suppliers and partners, and the effectiveness of their management systems, based on periodic evaluation and feedback of their performance.

The organization should continually review and strengthen its relationships with its suppliers and partners, while considering the balance between its short- and long-term objectives.

Clause 8.4.2 – Type and extent of control

What does this mean?

The organisation must ensure that:

- processes, products and services provided by external entities, do not adversely affect the organisation's ability to consistently deliver conforming products and services to its customers
- externally provided processes remain within the control of the organisation's QMS that controls that will be applied to the external provider(s) are defined
- that controls that will be applied to the resulting outputs of the externally provided process are defined
- the potential impact that externally provided processes, products and services have on the customer and legal requirements are taken into consideration
- the effectiveness of controls applied by the external provider is taken into consideration
- verification or other activities are done to ensure that requirements are met

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.4.2

Clause 6.4.1 - (Suppliers and partners) General See detail on page 70 (PM on page 70).

Clause 6.4.2 - (Suppliers and partners) Selection, evaluation and improvement of the capabilities of suppliers and partners See detail on page 71 (PM on page 70).

Clause 8.4.3 – Information for external providers

What does this mean?

The organisation must ensure that:

- that the client requirements are defined properly before they are communicated to the external provider
- the following is communicated to the external provider:

o the approval of products and services, methods, processes and equipment and the

release of products and service

o what competency level is required for persons in relation to the product production and

delivery

o interaction with the organisation

o control and monitoring of performance

o verification and validation activities will be performed at the external provider's premises

by the organisation or the customer

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.4.3

None

Clause 8.5 – Production and Service Provision

Clause 8.5.1 – Control of production and service provision

What does this mean?

Controlled conditions to be implemented for production and service provision include, as applicable:

- Documented information that defines the characteristics of the product**,** the services to be provided, the activities that need to be performed and the desired results.
- The availability and use of monitoring and measuring resources.
- The implementation of monitoring and measurement activities.
- The use of suitable infrastructure and environment.
- The appointment of competent persons.
- The validation/revalidation activities where output results cannot be verified.
- The implementation of actions to prevent human error.
- The implementation of release, delivery and post-delivery activities.5

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.5.1

None.

Clause 8.5.2 – Identification and traceability

What does this mean?

The organisation must ensure that:

- suitable activities to identify outputs after each production phase
- the identification of status of outputs throughout production and service provision
- the control of the unique identification of each output when traceability is a requirement
- documented information is maintained to enable traceability

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.5.2

None.

Clause 8.5.3 – Property belonging to customers or external providers

What does this mean?

The organisation must ensure:

- proper care of any belongings of customers or external providers while under the organisation's control
- that property of customers or external providers is identified, verified, protected and safeguarded
- that customer or external providers' property that was lost, damaged or found unsuitable for use is reported
- that documented information is retained in the instances mentioned above

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.5.3

None.

Clause 8.5.4 – Preservation

What does this mean?

The organisation must ensure that:

· the output of products or services is preserved to ensure that they still comply with the

requirements

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.5.4

None.

Clause 8.5.5 Post-delivery activities

What does this mean?

The organisation must consider the following when determining the post-delivery activities:

- Compliance with statutory and regulatory requirements.
- Potential undesired consequences associated with its products and services.
- The nature, use and intended lifetime of the product(s) and service(s).
- Customer requirements.
- Customer feedback.
- Post-delivery activities include maintenance services, warranty provisions, recycling, final disposal, etc.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.5.5

None

Clause 8.5.6 – Control of changes

What does this mean?

The organisation must ensure:

- review and control of changes to ensure compliance with requirements
- the retention of documented information where any changes were identified, including the review of changes, person authorising the change and actions arising from the review

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.5.6

None

Clause 8.6 – Release of Products and Services

What does this mean?

The organisation must ensure:

- verification at planned stages to verify product and service requirements compliance

- that no product/service is released prior to verification, unless authorised by a relevant authority and, as applicable, by the client
- that documented information is retained to proof conformity to acceptance criteria and traceability to person(s) authorising the release

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.6

Clause 8.2 - (Monitoring, measurement, analysis and review) Monitoring

"Top management should establish and maintain processes for monitoring the organisation's environment, and for collecting and managing the information that is necessary for:

- identifying and understanding the present and future needs and expectations of all relevant interested parties,
- assessing strengths, weaknesses, opportunities and threats,
- determining the need for alternative, competitive or new product offerings,
- evaluating current and emerging markets and technologies,
- anticipating current and expected changes in statutory and regulatory requirements,
- understanding the labour market and its effect on the loyalty of people in the organisation,
- understanding the social, economic, ecological trends and local cultural aspects relevant to the organisation's activities,
- determining the need for natural resources, and their protection over the long term, and
- assessing current organisational and process capabilities (see Annex A).

Clause 8.7 – Control of Nonconforming Outputs

What does this mean?

The organisation must ensure:

- the reporting of deviations of required outputs
- the prevention of the unintended use of nonconforming products or services
- appropriate action is taken based on the nature and effect of the nonconformity. This must be applied to nonconforming products and services identified after delivery, during or after service provision
- nonconforming outputs are dealt with in one or more of the following ways:
- correction

o segregation, containment, return or suspension of provision of products and services

o customer is informed

o concession is authorised if the decision is made to release the nonconforming product

- when nonconforming outputs are correct, conformity to the requirements must be verified
- Documented information must include the following details:

o a description of the nonconformity

o actions taken

o concessions obtained

o authority for actions that were taken in respect of the nonconformity

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 8.6

None.

Possible Challenges

- Keeping documented information of events such as changes and nonconformities.

4.6 CLAUSE 9 – PERFORMANCE EVALUATION

Applicable clauses

CLAUSE NO.	CLAUSE DESCRIPTION
9.1	Monitoring, measurement, analysis and evaluation
9.1.1	General
9.1.2	Customer satisfaction
9.1.3	Analysis and evaluation
9.2	Internal audit
9.3	Management review (Title only)
9.3.1	General
9.3.2	Management review inputs
9.3.3	Management review outputs
9.1	Monitoring, measurement, analysis and evaluation

ISO 9001:2015 Requirements – Clause 9 – Performance Evaluation

Clause 9.1 – Monitoring, Measurement, Analysis and Evaluation

Clause 9.1.1 – General

What does this mean?

The organisation shall determine:

- what needs to be monitored and measured
- what monitoring, measurement, analysis and evaluation methods shall be used to ensure valid results
- when monitoring and measurement will take place
- when results will be analysed and evaluated
- the performance and the effectiveness of the QMS
- documented information is retained to proof evaluation of effectiveness and evidence of results

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 9.1.1

Clause 8.1 - (Monitoring, measurement, analysis and review) General See detail on page 57 (PM on page 56).

Clause 8.2 - (Monitoring, measurement, analysis and review) Monitoring See detail on page 74 (PM on page 74).

Clause 8.3.1 - (Measurement) General

"Top management should assess progress in achieving planned results against the mission, vision, policies strategies and objectives, at all levels and in all relevant processes and functions in the organization. A measurement and analysis process should be used to monitor this progress, to gather and provide the information necessary for performance evaluations and effective decision-making.
The selection of appropriate key performance indicators and monitoring methodology is critical for success of the measurement and analysis process.

The methods used for collecting information regarding key performance indicators should be practicable and appropriate to the organization. Typical examples include:

- risk assessments and risk controls,
- interviews, questionnaires and surveys on customer and other interested parties' satisfaction,
- benchmarking,
- performance reviews, including suppliers and partners, and
- monitoring and recording of process variables and product characteristics.

Clause 9.1.2 – Customer satisfaction

What does this mean?

The organisation shall ensure that:

- the degree of satisfaction of the client is monitored
- methods for obtaining this information are defined, for example, customer surveys, feedback on delivered products and services, meetings, market-share analysis, compliments, warranty claims, etc.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 9.1.2

Clause 8.3.1 - (Measurement) General See detail on page 76 (PM on page 76).

Clause 9.1.3 – Analysis and evaluation

What does this mean?

The results of analysis of data and information shall be used to evaluate the following:

- product/service conformity
- the degree of customer satisfaction
- the performance and effectiveness of the QMS
- effective implementation of planning.
- effectiveness of actions to address risks and opportunities
- the performance of external providers

- the need for improvement of the QMS

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 9.1.3

Clause 8.4 - (Monitoring, measurement, analysis and review) Analysis

"Top management should analyse information gathered from monitoring the organization's environment, identify risks and opportunities, and establish plans to manage them. The organization should monitor and maintain relevant information, and analyse potential impacts on its strategy and policies.

The analysis of the information gathered should enable factual decisions to be made on strategy and policy issues such as:

- potential changes in the needs and expectations of interested parties in the long term,
- those existing products and activities that currently provide the most value for its interested parties,
- new products and processes needed to meet the changing needs and expectations of its interested parties,
- the evolving demands for the organizations' products in the long term,
- the influence of emerging technologies on the organization,
- new competences that could be needed, and
- changes that can be expected in statutory and regulatory requirements, or labour markets and other resources, which would affect the organization.

Clause 9.2 – Internal Audit

What does this mean?

- An audit programme must be implemented to determine if the QMS:

o conforms to the organisation's requirements for the QMS
o complies with the ISO 9001:2015 standard requirements
o is implemented and maintained effectively

- An audit programme must be established, implemented and maintained, including the frequency, methods, responsibilities, planning requirements and reporting on results of audit findings.
- Audit criteria and scope must be defined.
- Auditors must be selected to ensure objectivity and impartial during the audit process. Results of the audits must be reported to relevant management.
- Appropriate corrections and corrective action(s) must be taken without undue delay.
- Documented information is retained to prove that the audit programme was implemented. Audit results must also be retained.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 9.2

Clause 8.3.3 - (Monitoring, measurement, analysis and review) Internal Audit

"Internal audits are an effective tool for determining the levels of compliance of the organization's management system against given criteria, and provide valuable information for understanding, analysing and continually improving the organization's performance. Audits should be conducted by people who are not involved in the activity being examined, in order to give an independent view on what is being performed.

Internal audits should assess the implementation and effectiveness of the management system. They can include auditing against more than one management system standard, such as ISO 9001 (quality management) and ISO 14001 (environmental management), as well as addressing specific requirements relating to customers, products, processes or specific issues.

To be effective, internal audits should be conducted in a consistent manner, by competent personnel, in accordance with an audit plan.

Internal auditing is an effective tool for identifying problems, risks and nonconformities, as well as for monitoring progress in closing previously identified nonconformities (which should have been addressed through root cause analysis and the development and implementation of corrective and preventive action plans). Verification that the actions taken have been effective can be determined through an assessment of the improved ability of the organization to fulfil its objectives. Internal auditing can also be focused on the identification of good practices (that can be considered for use in other areas of the organization) as well as on improvement opportunities.

The outputs of internal audits provide a useful source of information for:

- addressing problems and nonconformities,
- benchmarking,
- promoting good practices within the organization, and
- increasing understanding of the interactions between processes.

The results of internal audits are usually presented in the form of reports containing information on compliance against the given criteria, nonconformities, and improvement opportunities. Audit reports are also an essential input for management reviews. Top management should establish a process for the review of all internal audit reports, to identify trends that can require organization-wide corrective or preventive actions.

The organization should also take the results of other audits, such as second and third party audits, as feedback for corrective and preventive actions.

Clause 9.3 – Management Review

Clause 9.3.1 – General

What does this mean?

The organisation shall ensure that:

- the QMS is reviewed at planned intervals to ensure its suitability, adequacy, effectiveness and alignment with the strategic direction of the organisation.

"Suitability" refers to how the EMS fits the organisation, its operations, culture and business systems.

"Adequacy" refers to whether it meets the requirements of this international standard and is implemented appropriately.

"Effectiveness" refers to whether it is achieving the desired results.

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 9.3.1

Clause 8.5 - (Monitoring, measurement, analysis and review) Review of information from monitoring, measurement and analysis

"Top management should use a systematic approach to reviewing available information and for ensuring that the information is used for decision-making (see 4.2).

Data can be collected from many sources, such as:

- monitoring of the organization's environment,
- measurements of the organization's performance, including key performance indicators,
- assessments of the integrity and validity of the measurement processes,
- results of internal audit, self-assessment and benchmarking activities,
- risk assessment, and
- feedback from customers and other interested parties.

The reviews should be used to evaluate the results achieved against applicable objectives.

Reviews should be performed at planned and periodic intervals, to enable trends to be determined, as well as to evaluate the organization's progress towards achieving its objectives. They should also be used to identify opportunities for improvement, innovation and learning. Reviews should address the assessment and evaluation of improvement activities performed previously, including aspects of adaptability, flexibility and responsiveness in relation to the organization's vision and objectives.

Effective reviews of data can assist in the achievement of planned results.

The outputs of reviews can be used for benchmarking internally between activities and processes and to show trends over time; they can be used externally against the results achieved by other organizations, in the same or other sectors.

The outputs of reviews can indicate the adequacy of resources provided, and how effectively resources have been used in achieving the organization's objectives.

The outputs of the reviews should be presented in a format that can facilitate the implementation of process improvement activities.

Clause 9.3.2 – Management Review Inputs

What does this mean?

The review must include consideration of:

- status of actions from previous reviews
- specific changes
- the achievement of environmental objectives
- environmental performance
- adequacy of resources
- communication from interested parties
- opportunities for continual improvement

ISO 9004:2009 linked clauses to ISO 9001:2015 Clause 9.3.1

Clause 8.5 - (Monitoring, measurement, analysis and review) Review of information from monitoring, measurement and analysis See detail on page 79 (PM on page 79).

Clause 9.3.3 – Management Review Outputs

What does this mean?

Outputs from the management review must include:

- decisions related to continual improvement opportunities
- decisions related to any need for changes to the EMS, including resources
- actions when objectives are not achieved
- opportunities to improve integration of the EMS with other business processes
- any implications for the strategic direction of the organisation

Evidence of the results of management reviews must be retained.

ISO 9004:2009 linked clauses linked clauses to ISO 9001:2015 Clause 9.3.3

Clause 8.5 - (Monitoring, measurement, analysis and review) Review of information from monitoring, measurement and analysis See detail on page 79 (PM on page 79).

Possible Challenges

- Management review is often not attended by all functional areas.
- Communication of the results of evaluation is often not done to all functional areas.
- Management review schedule is not adhered to.

Clause 10 – Improvement

Applicable clauses

CLAUSE NO.	CLAUSE DESCRIPTION
10.1	General
10.2	Nonconformity and corrective action
10.3	Continual Improvement

Annex A Clarification of new structure, terminology and concepts

Annex B Other international standards on quality management and quality management systems developed by ISO/TC 176

ISO 9001:2015 Requirements – Clause 10 – Improvement

Clause 10.1 – General

What does this mean?

The organisation shall ensure that:

- opportunities for improvement are identified and implemented to meet customer requirements and enhance customer satisfaction

- opportunities for improvement shall include those to meet requirements as well as those to address future needs and expectations, correction, prevention or reduction of undesired effects and those improving performance and effectiveness of the QMS

ISO 9004:2009 linked clauses linked clauses to ISO 9001:2015 Clause 10.1

Clause 9.1 - (Improvement, innovation and learning) General

"Depending on the organization's environment, improvement (of its current products, processes, etc.) and innovation (to develop new products, processes, etc.) could be necessary for sustained success.

Learning provides the basis for effective and efficient improvement and innovation.

Improvement, innovation and learning can be applied to:

- products,
- processes and their interfaces,
- organizational structures,
- management systems,
- human aspects and culture,
- infrastructure, work environment and technology, and
- relations with relevant interested parties.

Fundamental to effective and efficient improvement, innovation and learning is the ability and enablement of the people in the organization to make informed judgments on the basis of data analyses and the incorporation of lessons learned.

Clause 9.2 - Improvement, innovation and learning) Improvement

"Improvement activities can range from small-step continual improvements at a workplace to significant improvements of the entire organization.

The organization should define objectives for the improvement of its products, processes, organizational structures and its management system through the analysis of data.

The improvement processes should follow a structured approach, such as the "Plan-Do-Check-Act" (PDCA) methodology. The methodology should be applied, consistently with the process approach, for all processes.

The organization should ensure that continual improvement becomes established as a part of the organizational culture by:

- providing the opportunities for people in the organization to participate in improvement activities, through their empowerment,
- providing the necessary resources,
- establishing recognition and reward systems for improvement, and
- continual improvement of the effectiveness and efficiency of the improvement process itself.

Clause 10.2 – Nonconformity and Corrective Action

What does this mean?

The organisation must ensure that:

- it reacts to nonconformities, including complaints
- it takes action to control and correct nonconformities
- it deals with the consequences of nonconformities
- it evaluates the need for action to eliminate the cause(s) of nonconformity to prevent nonconformities from occurring again or elsewhere. Evaluation must include:

o review of an analysis of the nonconformity

o determine the causes of the nonconformity

o determine similar nonconformities exist, or could potentially occur

- it implements any actions required that are appropriate to the effects of the nonconformity
- it reviews the effectiveness of corrective actions
- it updates the risks and opportunities determine during the planning phase
- it makes changes to the QMS if necessary

ISO 9004:2009 linked clauses linked clauses to ISO 9001:2015 Clause 10.2

Clause 9.1 - (Improvement, innovation and learning) General See detail on page 82 (PM on page 81).

Clause 9.2 - (Improvement, innovation and learning) Improvement See detail on page 82 (PM on page 81).

Clause 10.3 – Continual Improvement

What does this mean?

The organisation must ensure that:

- the suitability, adequacy and effectiveness of the QMS are continually improved
- the results that were identified in Clause 9.1.3 (analysis and evaluation) and Clause 9.3 (management review), are used to determine needs or opportunities to continually improve the QMS

ISO 9004:2009 linked clauses linked clauses to ISO 9001:2015 Clause 10.3

Clause 9.1 - (Improvement, innovation and learning) General See detail on page 82 (PM on page 81).

Clause 9.2 - (Improvement, innovation and learning) Improvement See detail on page 82 (PM on page 81).

Possible Challenges

- Organisations must identify activities that can be implemented to **prevent** QMS nonconformities.
- More emphasis must be put on prevention, rather than correcting deviations.
- It often happens that determination of root causes of nonconformities is not done in a timely manner.
- Nonconformities are not always documented.
- Organisations can include "near misses" as nonconformities to include in trend analysis.

NEW THEMES	PHASE	CLAUSES	ACTIVITY	EVIDENCE TO SUPPORT CONFORMANCE
Business Planning and Strategic Direction	Plan	4.1, 4.2	Has the organisation identified both internal and external issues and interested parties that are relevant to and/or support the strategic direction of the organisation?	
	Do	5.2.1	Is the strategic direction being utilised as an input to the quality policy/quality objectives/risk management/management review processes?	
	Check	4.1, 4.2, 5.1.1, 9.3.2	Is the quality system being assessed and reviewed in accordance with the strategic direction?	
	Act	10.3	Is the quality system being updated, as necessary, in response to changes in any of the above?	
Process Risk	Plan	4.4.1, 6.1, 6.2, 6.3, 8.5.6	When establishing the QMS and planning for change, have risks to achieving process objectives been identified?	
	Do	8.1	Have the identified process risks been addressed?	
	Check	6.1.2, 9.1.3, 9.3.2	Is the organisation analysing the effectiveness of actions taken to address process risks?	
	Act	10.2.1, 10.3	Following analysis and corrective action is there evidence that process risks have been updated?	
Product and Service Risk	Plan	5.1.2, 6.1, 6.2 8.1, 8.2.2, 8.2.3 8.3.2	Have risks to achieving product or service conformity been: • considered as part of the planning for operational control? • considered when determining and reviewing customer requirements? • identified and has product complexity been considered during design planning?	

	Do	8.1, 8.2.3.1, 8.3.3	Have design and operational controls to address the identified product and service risks been implemented?	
	Check	9.1.3, 9.3.2	Is the organisation analysing the effectiveness of actions taken to address product risks?	
	Act	10.1	Has the organisation determined and selected opportunities for improvement on product and service?	
Risk associated with the control of externally provided product and service	Plan	6.1	Have risks associated with externally provided product, process (that is, formerly named outsourced) or service been identified?	
	Do	8.4.1, 8.4.2	Are the identified risks utilised as an input into the: • potential impact of externally provided product, process or service"? • type and extent of controls? • selection and evaluation of external providers? • degree of information provided to these resources?	
	Check	8.4.1, 9.3.2	Has the organisation applied criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?	
	Act	9.3.3	Has the organisation modified the controls applied to external providers based upon the results of evaluation?	

5 WHAT TO EXPECT FROM THE ISO 9001:2015 IMPLEMENTATION COURSE

During the ISO 9001:2015 Implementation course the following outcomes can be expected:

- Section 1: Revision of Introduction course
- Section 2: Understand the implementation of ISO 9001:2015
- Section 3: What to expect from the ISO 9001:2015 Auditing Course

NOTE: Bring along your ISO 9004:2009 standard. The ISO 9001:2015 standard will be provided during the implementation course.

