

ISO Management system standards

- An overview -

ISO Management systems

What are they? Why use them?

- Complying with ISO management standards:
 - increases confidence in business relationships,
 - broadens opportunities
 - satisfies many legal and contractual requirements
 - provide an international benchmark

ISO High level text – Annex SL

What is it? Why has it been introduced?

- Developed by ISO
- Introduces common clause headings & core text
- Increases alignment and makes it easier to implement multiple management systems
- Recognises that no two organizations operate in the same way – greater flexibility
- ISO 9001, 14001, 27001, 55001, 45001, 22301 all adopting this structure



Key Changes

- Emphasis on the context of the organization
- Application of risk based thinking
- Increased involvement and accountability of top management
- Integration of the management system into overall business strategy & systems
- Greater emphasis on the customer and communications
- Less bureaucracy



The Common Structure

All management standards will follow the same structure

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



Clause 4. Context of the organization

What is the context of the organization?

Who are the interested parties?

- context refers to the situation an organization operates in and anything which affects its operations
- interested parties are those individuals or entities which are affected by the organization and its products or services

Organizations need to be proactive in assessing their situation and determining the risks and opportunities it presents.



Clause 5. Leadership

Other than the title, what else has changed?

- increased emphasis on top management being accountable for the *effectiveness* of management systems
- a requirement that management systems are aligned to top level business objectives and integrated into business processes
- no longer possible to make the quality/environment/health and safety manager solely responsible for establishing, implementing and maintaining the management system



Clause 6. Planning

Risk based thinking...

- risk has always been implicit in these standards
- risks and opportunities have to be identified and addressed
- formal risk management not a requirement
- system focused on prevention
- New requirements to manage change (ISO 9001)



Clause 7.5 Documented Information



What happened to procedures, records & manuals?

- use of “documented information” to reflect current ways of working & all media
- less prescriptive on what is needed – up to the organization to demonstrate effectiveness of system
- “retain” equates to records
- “maintain” equates to something that is kept up to date i.e. procedures, plans



Specific needs

If there is a common structure where do the differences come in?

- every management system standard will include *specific requirements related to the subject*
- the common structure and core text provides a *generic framework*: it is expected and desirable that for some sectors *very prescriptive requirements will be added* to ensure safety, etc
- in some sectors *basic terminology* may not be *appropriate* and therefore drafters may seek a change
- clause *emphasis will vary* from sector to sector



ISO 9001 Key changes

- Management representative – no specific requirement
- explicit reference to 'products and services' throughout
- Exclusions are not directly referred to - apply all requirements of the standard unless the context of the organization clearly identifies that they cannot be applied
- Organizational knowledge - there is now a requirement to determine and manage
- More explicit design and development requirements making it clearer when exclusions are acceptable
- Planning of Changes to QMS – new requirement



ISO 14001 – Key changes

- considers environment as a whole, not just pollution
- does not define 'protect the environment'
- considers effect of the environment on the organization and organization's effect on the environment
- longer-term challenge vs short-term internal resource constraints
- life-cycle perspective and value-chain
- striking a balance on material environmental issues: control vs influence
- increased emphasis on knowledge and understanding of compliance status



ISO 45001 – What to expect

- publication is due October 2016
- the key changes from OHSAS 18001 to ISO 45001 are through the common structure and core text
- issues still being debated include the use of the term 'worker' and the definition of 'workplace'
- as in ISO 14001 the clause on planning is key and includes focus on legal and other requirements as well as general consideration of risks
- emphasis on both risks and opportunities related to health and well-being and to the management system itself



Conclusions

- existing proactive management systems are probably already meeting most of the requirements of the new standards
- will not be able to treat quality, environment or health and safety as tick-box exercises
- increased alignment of the management system standards will make implementation easier and more effective
- don't wait to begin identifying where the gaps are
- plan for necessary changes and implement those changes as soon as possible



More information

- NSAI website – www.n Sai .ie
- www.iso.org/tc176/sc2/public
- Participate in standard committees
Contact: linda.hendy@nsai.ie



Thank you

Questions later



NSAI

ISO 9001:2015 Revision Overview

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ISO 9001:2015 Contents

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
 - Understanding the organization and its context
 - Understanding the needs and expectations of interested parties
 - Determining the scope Of QMS
 - Quality management system and its processes
5. **Leadership**
 - Leadership and commitment
 - Quality Policy
 - Organizational roles, responsibilities and authorities
6. **Planning**
 - Actions to address risks and opportunities
 - Quality objectives and planning to achieve them
 - Planning of changes
7. **Support**
 - Resources
 - Competence
 - Awareness
 - Communication
 - Documented information
8. **Operation**
 - Operational planning and control
 - Requirements for products and services
 - Design and development of products and services
 - Control of externally provided processes, products and services
 - Production and service provision
 - Release of products and services
 - Control of nonconforming outputs
9. **Performance evaluation**
 - Monitoring, measurement, analysis and evaluation
 - Internal audit
 - Management review
10. **Improvement**
 - General
 - Nonconformity and corrective action
 - Continual improvement



NSAI

Introduction

Clause 0.1 – General

- Additional potential benefits from implementing a QMS are:-
 - Addressing risks and opportunities associated with its context and objectives,
 - Facilitating opportunities to enhance customer satisfaction.

Clause 0.2 - Quality management principles

Clause 0.3 –Process approach

- 0.3.1 – General
- 0.3.2 – Plan-Do-Check-Act cycle
New diagram for clauses 4 to 10, no changes
- 0.3.3 – Risk-based thinking

Clause 0.4

Relationship with other management system standards

- Adopts the “High Level Structure” of Annex SL, 10 Clauses.
- Enables an organisation to align or integrate its QMS with the requirements of other management system standards.



0.2 Quality Management Principles

7 QMP (2015)

- Customer focus
- Leadership
- Engagement of people
- Process Approach
- Improvement
- Evidence based Decision Making
- Relationship Management

QMP'S described in ISO 9000

8 QMP (2008)

- Customer focus
- Leadership
- Involvement of people
- Process Approach
- System approach to management
- Continual Improvement
- Factual approach to Decision Making
- Mutual beneficial Supplier Relationships



Introduction

Clause 0.3 - Process approach

- Promotes the process approach beyond the existing requirements.
- The application of the process approach will vary from one organisation to another, depending on its size, complexity and activities.
- Organisations often identify procedures rather than a process.
- Requirements for adopting a process approach can be found in [Clause 4.4](#).
- Includes inputs required and the outputs expected from the processes, also the sequence and interaction of the processes. Inputs / outputs can be grouped into four general categories: products, services, resources, and information.
- Including increased focus on measurements and related performance indicators needed to ensure the effective operation and control of the processes.



Assembly Process Model

A different example is shown below for an assembly process; this would be repeated for all the other processes in the organisation.

Assembly Process Owners	
Position	
Production Manager	
Production Supervisors	
Process Engineer	

QMS Procedures / Documents	
QP08	Control of Non-Conformance
OP09	In process Inspection of Product
OP11	Packaging of Product
OP12	Scheduling
OP15	Assembly Work Instruction
CM01	Competency Matrix
ETC.	



Assembly Process Model

From Process	Inputs	Assembly Process	Outputs	To Process
QA Test	Quality Plan Records		Assembled Products	QA Test
Material Control	Materials		Quality Plan Records	QA Test
Product Engineering	Drawings		Completed Control Charts	Data Analysis
Product Engineering	Machine Programs		Non-conforming products	Rework & Repair
Order Review & Scheduling	Production Schedule			
Product Engineering	Control Charts			
Resource Management	Manpower			

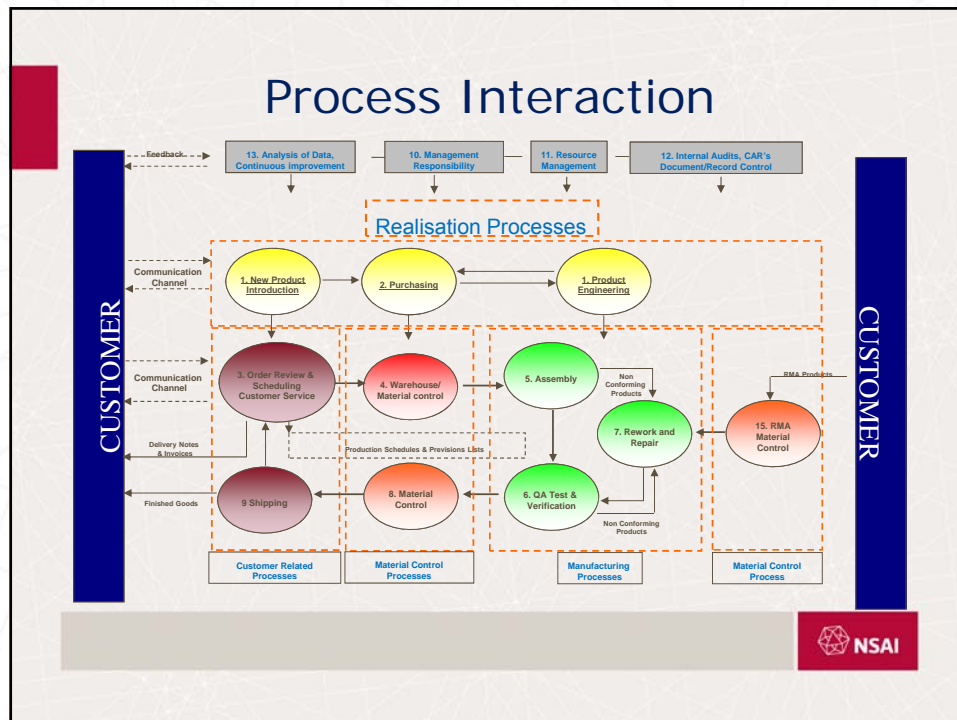


Assembly Process Model



Measurement	Target
First Pass Yield	≥ 98%
RMA	≤ 500 DPPM
Machine Utilisation	86%
On time delivery to customer	≤ 3 days
Absenteeism	3.5%





Introduction

Clause 0.3.3 - Risk-based thinking

Organisations need to plan and implement actions to address risks and opportunities. Risk is the effect of uncertainty on an expected result and the concept of risk-based thinking has always been implicit in ISO 9001.

- In **Clause 4** the organisation is required to determine the risks which can affect its ability to meet the objectives. The consequences of risk are not the same for all organisations, for some the delivery of a non-conforming product or service is minor for others it can be fatal, it depends on the business context.
- In **Clause 5** top management is required to demonstrate leadership and commitment to ensure that risks and opportunities that can effect the conformity of a product or service are determined and addressed.
- In **Clause 6** the organisation is required to take action to identify risks and opportunities, and plan how to address them.
- In **Clause 8** the organisation is required to plan, implement and control its processes to address the actions identified in **Clause 6**.
- In **Clause 9** the organisation is required to monitor, measure, analyse and evaluate the risks and opportunities.
- In **Clause 10** the organisation is required to improve by responding to changes in risk.
- So in effect we have the **Plan, Do, Check, Act** cycle applied to risk.

Quality Management System Requirements

Clause 1 Scope

- Scope is not changed,
- Removed allowed exclusions to the scope.
- Requirement for justification of a clause that cannot be applied is found in [Clause 4.3](#) Determining scope of QMS.

Clause 2 Normative references

- ISO 9000:2015 Quality management systems
 - fundamentals and vocabulary

Clause 3 Terms and definitions

- The terms and definitions given in ISO9000:2015 apply, along with new terms that have been added, such as: - performance, interested parties, risk, etc.



Clause 4 - Context of the organisation

Clause 4.1

Understanding the organisation and its context

Clause 4.2

Understanding the needs and expectations of interested parties

Clause 4.3

Determining the scope of the quality management system

Clause 4.4

Quality management system and its processes



Clause 4 - Context of the organisation

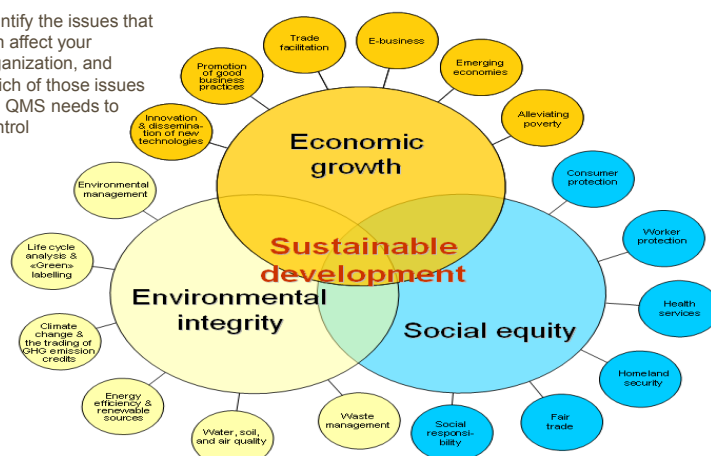
Clause 4.1 - Understanding the organisation and its context

- This is a new requirement and a very important one, because it is necessary to obtain an overview of the organisation to understand the quality challenges of the organisation, and the risk inherent in their sector.
- The organisation should determine the (positive and negative) internal and external factors that will / can effect them, to determine the issues that are relevant, and can prevent the success of the QMS implementation, such as:-
 - External:- regulation, technological, competitive, market, cultural, stakeholders, social, and economic environment (exchange rate),
 - Internal:- values, culture, knowledge, and organisation performance.



Clause 4 - Context of the organisation

Identify the issues that can affect your organization, and which of those issues the QMS needs to control



Clause 4 - Context of the organisation

Clause 4.2

Understanding the needs and expectations of interested parties

- The organisation shall determine:-
 - The interested parties that are relevant to the QMS,
 - The requirements of these interested parties that are relevant to the QMS.
- Identification and analysis the requirements and expectations of interested parties, e.g.: - Organisation, Board of Directors, Management Team, Employees, Unions, Customers, Suppliers, Financial Institutions, Interested Groups, Shareholders, Public, Media, Legislator, etc.
- Validate requirements and expectations, determining what is relevant or not relevant is dependant on whether or not it has an impact on the organisations ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.



Clause 4 - Context of the organisation

Clause 4.3 - Determining the scope of the quality management system

- Requirements to determine the scope are more extensive, the standard sets the requirements relating to scope boundaries.
- The term “exclusion” was replaced by “requirement that cannot be applied”, all clauses of ISO 9001 are mandatory, and can only be excluded if a clause cannot be applied. Where a requirement of this International Standard within the determined scope can be applied, then it shall be applied by the organization.
- The scope shall state the justification for any instance where a requirement of this standard cannot be applied, and conformity to this standard may only be claimed if the requirement that cannot be applied does not affect the organisations ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.
- Consider the following when determining the scope:-
 - external and internal issues referred to in **Clause 4.1**,
 - requirements of relevant interested parties referred to in **Clause 4.2**,
 - and the products and services of the organisation.



Clause 4 - Context of the organisation

Increased emphasis on achieving value for the organisation and its customers

- **Providing product and services that meet customers and statutory requirements still the primary focus**

- Meeting Customer Requirements
- Aims to enhance customer satisfaction



Clause 4 - Context of the organisation

Clause 4.4 – Quality Management System and its processes

- Process approach is more explicit than in 2008 edition.
- Includes inputs required and the outputs expected from the processes, also the sequence and interaction of the processes.
- Including increased focus on measurements and related performance indicators needed to ensure the effective operation and control of the processes.
- The assignment of the responsibility and authority for the processes, and availability of necessary resources.
- Must determine and address process related risks and opportunities, implement appropriate action to address them.
- Outsourcing moved to [Clause 8.1](#) and [8.4](#).
- The organisation shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned.



Clause 5 - Leadership

Clause 5.1

Leadership and commitment

Clause 5.2

Policy

Clause 5.3

Organisational roles, responsibilities and authorities



Clause 5 - Leadership

Clause 5.1 – Leadership and commitment

- Title changed from “Management commitment” to “Leadership and commitment.”
- New high level structure places particular emphasis on leadership requirements / engagement.
- This means top management has now greater accountable and involvement:-
 - for the effectiveness of the QMS,
 - integration of the QMS requirements into the organisations business processes
 - promoting awareness of the process approach,
 - ensuring that risks and opportunities that can affect conformity are addressed,
 - and to the needs and expectations of its customers.



Clause 5 - Leadership

Clause 5.2 – Quality Policy

- Quality policy basically unchanged, emphasis on communication.

Clause 5.3 – Organisational roles, responsibilities and authorities

- No requirement for a management representative, yet the responsibilities and authorities still remain.
- including:
 - that processes are delivering their intended outputs,
 - promotion of customer focus,
 - reporting on the performance of the QMS
 - ensuring the integrity of the QMS is maintained during changes.



Clause 6 – Planning for the Quality Management System

Clause 6.1

Actions to address risks and opportunities

Clause 6.2

Quality objectives and planning to achieve them

Clause 6.3

Planning of changes



Clause 6 – Planning for the Quality Management System

Clause 6.1 – Actions to address risks and opportunities

- One of the key purposes of a QMS is to act as a preventive tool, and to enhance desirable effects.
- One of the key changes is to replace “preventive action” with a systematic approach to risk / risk- based thinking. Instead of being part of the preventive action procedure, risk is considered throughout the QMS.
- Once the organisation has highlighted risk and opportunities in [Clause 4](#), it needs to decide how these will be address through planning.
- By preventing or reducing the undesirable effects, this proactive approach replaces preventive action and reduces the need for corrective action later on (reactive approach). Risk based thinking can also help to identify opportunities, risk can be positive as well as negative, e.g.: - attract new customers, develop new products and services, reduce waste, improve productivity, geographical expansion, new technologies.
- Top management should be able to demonstrate an understanding of business risks and how they could impact on the ability to meet customer requirements.
- Option to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminate the risk source, change the likelihood or consequence, sharing the risk, or retaining risk by informed decision.



Clause 6 Planning for the Quality Management System

Clause 6.2 – Quality objectives and planning to achieve them

- More emphasis on objectives.
- Sets out clearer requirements on planning, when establishing quality objectives you need to demonstrate how you plan to achieve them.
- The planning phase looks at what, who, how, resources needed, and when these risks must be addressed, and how the results will be assessed.
- Quality objectives can be technical, strategic or operational.



Clause 6 Planning for the Quality Management System

Clause 6.3 – Planning of changes

- More emphasis on controlling changes.
- Additional requirements: -
 - When the organisation determines the need for change to the QMS, the changes will be carried out in a planned systematic manner, and shall consider: - purpose and potential consequences, integrity of the QMS, availability of resources, and responsibilities and authorities.



Clause 7 – Support

Clause 7.1

Resources

Clause 7.2

Competence

Clause 7.3

Awareness

Clause 7.4

Communication

Clause 7.5

Documented information



Clause 7 – Support

Clause 7.1 Resources

Clause 7.1.1 General

- Organisation to consider capabilities and constraints of existing internal resources and what needs to be obtained from external resources.

Clause 7.1.2 People

- The term people replaces human resources.

Clause 7.1.3 Infrastructure

- No changes.

Clause 7.1.4 Environment for the operation of processes

- Used to be “Work environment”.
- Need to identify and maintain the environment that your organisation needs in order to support process operations and to achieve conformity of products and services.



Clause 7 – Support

Clause 7.1.5 – Monitoring and measuring resources

- “Equipment” has been replaced by “resources”,
- Resources include work tools, human resources, test methods, software, etc. This may have a big impact for service organisations, which may have previously excluded Clause 7.6 Control of monitoring and measuring equipment.
- Organisations need to determine the suitability of the resources and retain documentary evidence of fitness for their purpose.
- Acknowledgement that professional judgement ,software, etc. may also be a measuring resource
- Less descriptive on calibration.



Clause 7 – Support

Clause 7.1.6 – Organisational knowledge (new sub-clause)

- Organisations have to determine the knowledge it needs for the operation of its processes and to achieve conformity of products and services.
- Has to obtain and maintain that knowledge, and make available as necessary (internal or external).
- When addressing changing needs or trends, the organisation shall consider current knowledge and determine how to obtain necessary additional knowledge.
- Knowledge is gained by experience, its information that is used and shared, intellectual, lessons learnt from past experience.
- External sources: obtained from customers, external providers, conferences, academia.



Clause 7 – Support

Clause 7.2 – Competence

- “Competence” replaces “Competence, training and awareness”.
- Extension of competence from those whose “work affecting conformity to product requirements” to “affects its quality performance”. Includes external resources.
- A note is included to explain applicable actions can include: - provision of training, mentoring, hiring or contracting of competent persons.

Clause 7.3 – Awareness

- Awareness now includes the quality policy, quality objectives, contribution to effectiveness of QMS, benefits of improved quality performance and implications of non-conforming with the QMS requirements.
- There is an increased emphasis on awareness to ensure that everyone knows the implications of not conforming to the QMS.
- An employee who is not aware or untrained represents a potential risk.



Clause 7 – Support

Clause 7.4 – Communication

- “Communication” replaces “Internal communication”, and includes internal and external communications relevant to the QMS.
- Develop a communications plan, which can include a variety of mediums including: briefings, seminars, newsletters, noticeboards, conferences.
- Requires the organisation to determine the what, when, with whom, how, and who communicates.
- Customer communication is addressed in **Clause 8.2.1**, as it determines the requirements for products and services.



Clause 7 – Support

Clause 7.5 – Documented information

- The term “documented information” replaces “documentation”, “documented procedure” and “records”.
- Fewer prescriptive requirements, no requirement for quality manual or documented procedures.
- But documented procedures could be seen as one form of risk control.
- The QMS shall include documented information determined by the organisation as being necessary for the effectiveness of the QMS.
- It does require “documented information to be either maintained (procedure) or retained (record), documented information is mandatory on clauses 4.3, 4.4, 5.2.2, 6.2.1, 7.1.6, 7.2, 7.5.1, 8.1, 8.2.3, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.5.1, 8.5.2, 8.5.6, 8.6, 8.7, 9.1.1, 9.2, 9.3, 10.2.
- More flexibility on the type of documents, format must be appropriate, can be in any format and on any medium and can come from any source. Documented information must be controlled, as before.



Clause 8 – Operation

Clause 8.1

Operation planning and control

Clause 8.2

Requirements for products and services

Clause 8.3

Design and development of products and services

Clause 8.4

Control of externally provided processes, products and services

Clause 8.5

Production and service provision

Clause 8.6

Release of products and services

Clause 8.7

Control of nonconforming outputs



Clause 8 – Operation

- “Products and services” replaces “product”.
- The term “products and services” includes all output categories, hardware, services, software and processed materials.
- Deals with the execution of the plans and processes.

Clause 8.1 – Operation planning and control

- “Product realisation” has been replaced with “operation”.
- There are a number of new requirements: -
 - inclusion of action to address risk and opportunity,
 - addressing control of planned changes,
 - reviewing consequences of unintended changes,
 - taking action to diminish adverse effects.



Clause 8 – Operation

Clause 8.2 Requirements for products and services

Clause 8.2.1 - Customer communication

- Includes the handling and treatment of customer property, if applicable.

Clause 8.2.2

Determination the requirements for products and services

- Rewording.
- Organisation has the ability to meet the claims for the product and services it offers.

Clause 8.2.3 - Review of the requirements for products an services

- Rewording.
- New note: Requirements can also include those arising from relevant interested parties.

Clause 8.2.4 - Changes to requirements for products and services

- Organisation shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.



Clause 8 – Operation

Clause 8.3 – Design and development of products and services

- “Design and development” changed to “Design and development of products and services”.

Clause 8.3.1 – General (New sub clause)

- The organisation shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.



Clause 8 – Operation

Clause 8.3.2 – Design and development planning

- There are a number of new items to be considered:-
 - the nature, duration and complexity of the activities,
 - Internal and external resources needed,
 - The requirements for subsequent provision of products and services
 - the need for involvement of customer and user groups,
 - the necessary documented information to confirm that requirements have been met.

Clause 8.3.3 – Design and development inputs

- There are a number of new items to be determined:-
 - standards or codes of practice that the organisation has committed to implement,
 - Information derived from previous similar design and development activities,
 - Internal and external resources needed,
 - Potential consequences of failure due to the nature of the product or service,



Clause 8 – Operation

Clause 8.3.4 – Design and development controls

- Combines three clauses of ISO 9001:2008, “Design and development review”, “Design and development verification” and “Design and development validation”.

Clause 8.3.5 – Design and development outputs

- Includes or reference monitoring and measurement requirement.
- Shall retain documented information resulting from the design and development process.

Clause 8.3.6 – Design and development changes

- “Control of design and development changes” replaced by “Design and development changes”.
- Shall review and control changes made to design inputs and outputs, to the extent that there is no adverse impact on conformity to requirements.



Clause 8 – Operation

Clause 8.4

Control of externally provided processes, products and services

- Externally provided / provider replaces purchasing, purchased and suppliers.
- Acknowledges the trend towards greater use of subcontractors and outsourcing

Clause 8.4.1 – General

- Controls are to be provided for the following: -
 - products and services that are provided by external providers for incorporation into the organisation's own products and services,
 - products and services that are provided directly to the customer by the external provider on behalf of the organisation,
 - outsourcing a process or function or part of a process or function to an external provider.
- External provision, includes associated companies



Clause 8 – Operation

8.4.2 – Type and extent of control

- Organisations shall: -
 - Ensure that externally provided processes remain within the control of its QMS
 - Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output,
 - Consider the potential impact of the externally provided processes, products and services on its ability to consistently meet customer and statutory and regulatory requirements,
 - Consider the effectiveness of the controls applied by the external provider,
 - Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 – Information for external providers

- Replaces "Purchasing information".
- Includes :- Communicating the control and monitoring of the external provider's performance to be applied by the organisation.



Clause 8 – Operation

8.5 Production and service provision

8.5.1 – Control of production and service provision

- Includes the requirements of ISO 9001:2008 Clauses “7.5.1 Control of production and service provision” and “7.5.2 Validation of processes for production and service provision”.
- The requirement for work instructions has been replaced by Documented information.

8.5.2 – Identification and traceability

- No new requirements.

8.5.3 – Property belonging to customers or external providers

- Replaces “Customer property”.
- Requires organisations to take care of property from external providers as well as customers.



Clause 8 – Operation

8.5.4 – Preservation

- Replaces Preservation of product.
- Now includes transmission (information, software).

8.5.5 – Post-delivery activities (New sub clause)

- Identify the activities that must be carried out after product or service delivery, such as: warranty, maintenance services, recycling, final disposal.

8.5.6 – Control of changes (New sub clause)

- The organisation shall review and control unplanned changes essential for production or service provision.
- Document: results review, actions taken, and who authorised the change.



Clause 8 – Operation

Clause 8.6 – Release of products and services

- Replaces “Monitoring and measurement of product”.
- No new requirements.

Clause 8.7 - Control of nonconforming outputs

- Replaces “Control of nonconforming product”.
- No requirement for a documented procedure. But there is a requirement to maintain documented information.
- When dealing with nonconforming product or service, the organisation needs to consider:-
 - segregation, containment, return or suspension,
 - informing the customer,
 - authorise re-provision of the products and services.



Clause 9 – Performance Evaluation

Clause 9.1

Monitoring, measurement, analysis and evaluation

Clause 9.2

Internal audit

Clause 9.3

Management review



Clause 9 – Performance Evaluation

Clause 9.1 – Monitoring, measurement, analysis and evaluation

- More emphasis on monitoring and measurement.
- Requirement for performance indicators for the QMS.
- Organisations need to plan, how and when they're going to monitor, measure, analyse, and evaluate their QMS.
- And then implement their monitoring and measurement activities.
- Organisations must show how the analysis and evaluation of data is used, with regards to the need for improvements to QMS.
- A key tool in driving the QMS is to enhance customer satisfaction.

Clause 9.2 – Internal audit

- No requirement for documented procedure.
- Some slight modifications to the requirements.
- Take into consideration changes to the organisation.



Clause 9 – Performance Evaluation

Clause 9.3 – Management Review

Looks at whether the management system is suitable, adequate and effective, items to be reviewed under management review include:-

- Take into consideration strategic direction of the organisation,
- Changes in external and internal issues relevant to QMS,
- Trends and indicators for: customer satisfaction, issues concerning external providers and other relevant interested parties, adequacy of resources, process performance and conformity of products and services,
- Effectiveness of action taken to address risk and opportunities,
- New potential opportunities for continual improvement.



Clause 10 – Improvement

Clause 10.1

General

Clause 10.2

Nonconformity and corrective action

Clause 10.3

Continual improvement



Clause 10 – Improvement

Clause 10.1 – General (New sub clause)

- Contains requirements from clause 8 of 9001:2008, pays more attention to improvement, includes improvement to processes, product or service and QMS.
- Select opportunities for improvement – meet customer requirements and enhance customer satisfaction.

Clause 10.2 – Nonconformity and corrective action

- Does not include a clause on Preventive action as an emphasis on risk-based thinking throughout the standard supersedes a single clause on preventive action.
- Additional requirements include, taking action to control and correct nonconformity and address the consequences, determining if similar nonconformities exist or could happen, making changes to QMS if necessary.
- Need a proactive corrective action process.



Clause 10 – Improvement

Clause 10.3 – Continual improvement

- The organisation shall continually improve the suitability, adequacy and effectiveness of the QMS.
- Areas of underperformance or opportunities shall be addressed as part of continual improvement.
- The organisation shall select and utilise applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.
- Need to be able to demonstrate that outputs from analysis & evaluation processes are used to make changes to the QMS if necessary



Guidance

- **Annex A** - Clarification of new structure, terminology and concepts
- **Annex B** – Other International Standards on quality management and quality management system developed by ISO/TC 176
- TS9002 Implementation Guide
- Small Business Handbook
- **Correlation matrices between ISO 9001:2008 and ISO 9001:2015**
This is available along with other information regarding the revision from the link below:
- www.iso.org/tc176/sc02/public

