INTERNATIONAL STANDARDS REGISTRAIONS

ISO 9001-2015 STANDARD (Property of International Standards Registrations)

Contents

ISO 9001-2015

INTRODUCTION

0.1 GENERAL

The adoption of a quality management is a strategic decision for an organization that can help to improve its overall performance and provide a sound basic for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this international standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
b) facilitating opportunities to enhance customer satisfaction;
c) addressing risk and opportunities associated with its context and objectives;
d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standards can be used by internal and external parties.

It is not the intent of this International Standards to imply the need for:

- uniformity in the structure of different quality management systems;
- alignment of documentation to the clause structure of this International standards;
- the use of the specific terminology of this International Standards with the organization.

The quality management systems requirements specified in this International Standards are complementary to requirements for products and services.

This International Standards employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk- based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk – based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in

place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see clause A4).

Consistently meeting requirements and future needs and expectation poses a challenge for organization in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International standards, the following verbal forms are used:

— "shall" indicates a requirement;

—"should" indicates a recommendation;

—"may" indicates a permission;

—"can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.2 QUALITY MANAGEMENT PRINCIPLES

This International Standards is based on the quality management principles in ISO 9000.The descriptions Include a statement of each principle, a rationale of why the principle and examination of typical action to improve the organization's performance when applying the principle.

The quality management principles are:

— customers focus

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision marking;

— relationship management .

0.3 PROCESS APPROACH

0.3.1 GENERAL

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

Understanding and meaning interrelated process as a system contributes to the organization's effectiveness and efficiency in achieving its intended result. This approach enables the organization's to control the interrelationship and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of process, and their interaction, so as to achieve the intended result in accordance with the quality policy and strategic direction of the organization. Management of the process 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 show the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

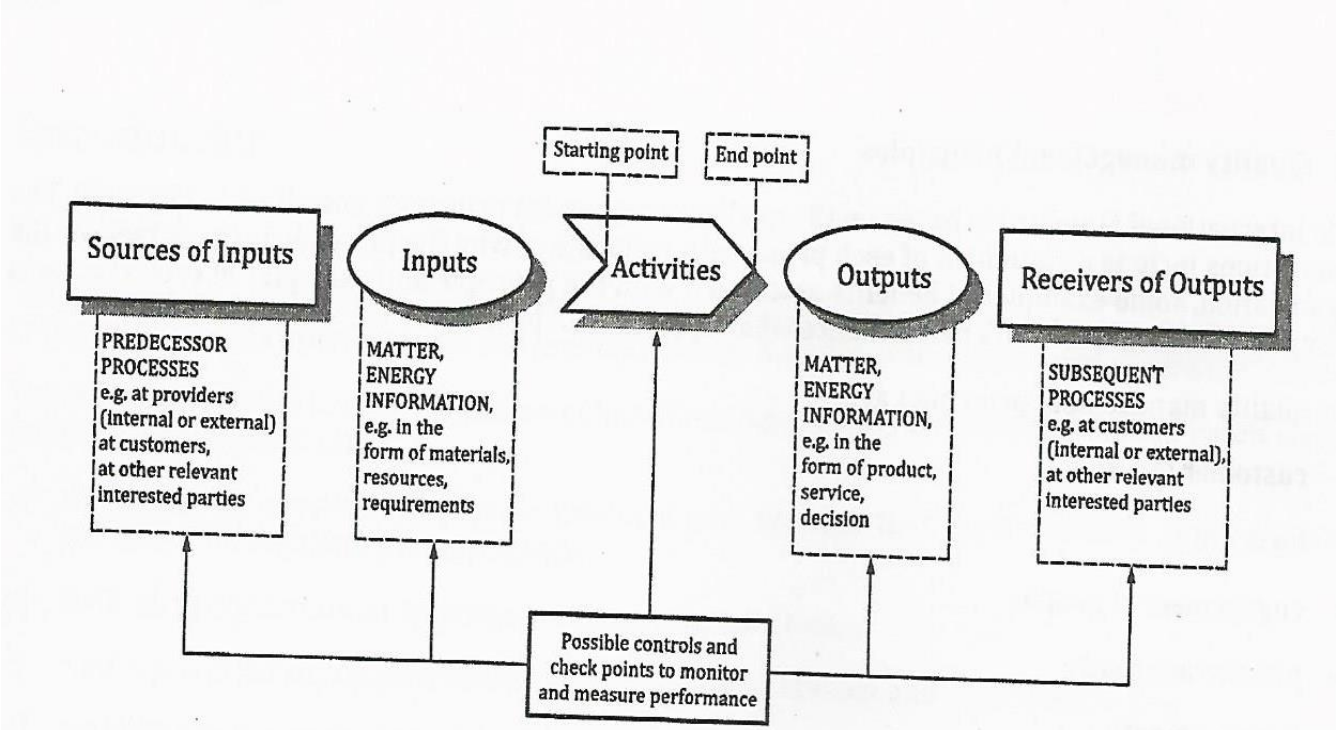
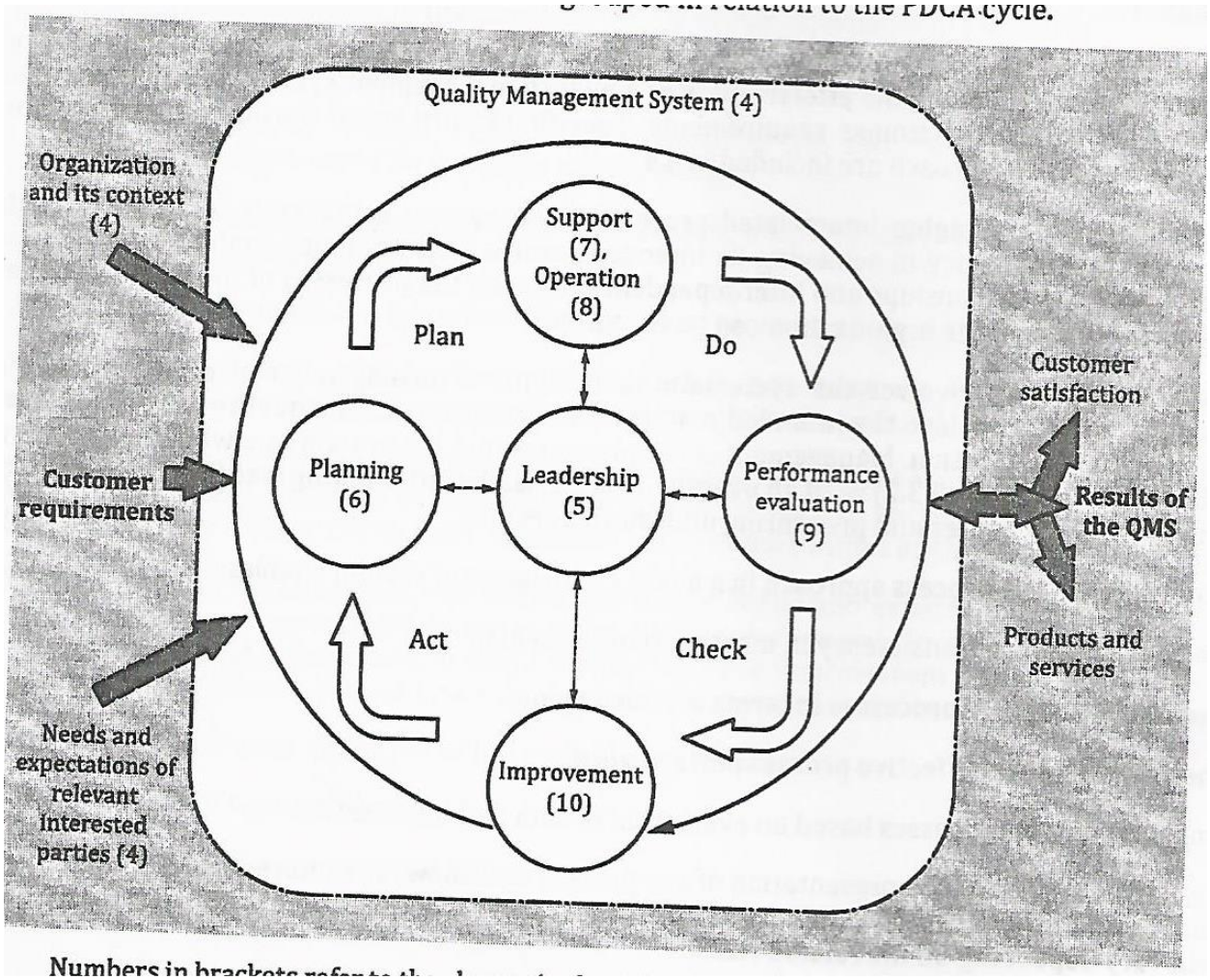


Figure 1 — Schematic representation of the elements of a single process

0.3.2 PLAN-DO-CHECK-ACT CYCLE

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



NOTE - Number in brackets refer to the clauses in this International standards.

Figure 2-representation of the structure of this International Standards in the PDCA cycle.

The PDCA cycle can be briefly described as follows:

— **Plain** : establish the objectives of the system and its processes, and the resources needed to deliver result in accordance with customers' requirement and the orgnizatio's policies, and identify and address risk and opportunities;

— **Do:** implement what was planned;

— **Check:** monitor and (where application) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the result;

— **Act:** take action to improve performance, as necessary.

0.3.3 risk-based thinking

Risk-based thinking (see clause-4) is essential for achieving an effective quality management system. The concept of risk- based thinking has been implicit in previous edition of this International Standards including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standards, an organization needs to plan and implement action to address risk and opportunities. Addressing both risk and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved result and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Action to address opportunities can also include consideration of associated risks. Risk is the effect or uncertainty and any such uncertainty can have positive or negative effects. A positive devlation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

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0.4 Relationship with other management system standards

This International Standards applies the framework developed by ISO to improve alignment among its International standards for management systems (see Clause A.1).

This International Standards enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standards relates to ISO 9000and ISO 9004 as follows:

— ISO 9000 Quality managements systems —- Fundamentals and vocabulary provides essential background for the proper understanding and implementation of this International Standards;

— ISO 9004 Managing for the sustained success of an organization —A quality management approach provides guidance for organization that chose to progress beyond the requirements of this International Standards.

QUALITY MANAGMENTS SYSTEMS –REQUIRMENTS

1. Scope

This International Standards specifies requirements for a quality management System when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

ALL the requirements of this International Standards are generic and are Intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standards, the terms “product” or “service” only apply to products and services intended, for or required by. A customer.

NOTE 2 statutory and regulatory requirements can be expressed as legal requirements.

2 Normative References

The following documents, in whole or in part, are normatively referenced in this documents and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of The referenced document (including any amendments) applies.
ISO 9000:2005, Quality management systems — Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

4 context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results(s) of its quality management system.

The organization shall monitor and review information about these external and internal issue.

NOTE 1 Issue can include positive and negative factors condition for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in **4.1**;
b) the requirements of relevant interested parties referred to in **4.2**
c) the products and services of the organization.

The organization shall apply all the requirements of this International Standards if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International

Standards that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standards may be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system and its processes

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the process needed and their interactions, in a accordance with the requirements of this International Standards.

The organization shall determine the process needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes.
b) determine the sequence and interaction of these processes;
c) determine and apply the criteria and methods (including monitoring measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d) determine the resources needed for these processes and ensure their availability;
e) assign the responsibilities and authorities for these processes;
f) address the risks and opportunities as determined in accordance with the requirements of **6.1 ;**
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
h) improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirement into the organization's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirement;
g) ensuring that the quality management system achieves its intended result;
h) engaging, directing and supporting person to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibleity.

NOTE: Reference to "business" in this International Standards can be interpreted to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.2 Customer focus

The management shall demonstrate leadership and commitment with respect to customer focus by ensuring that :

a) customer and application statutory and regulatory requirements are determined, understood and consistently met;
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;
b) provides a framework for setting quality objectives;
c) includes a commitment to satisfy application requirements;
a) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;
b) be communicated, understood and applied within the organization;
c) be available to relevant interested parties, as appropriate.

5.3 Organization roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirement of this International Standards;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the quality management system and on opportunities for improvement (see **10.1**) , in particular to top management;
d) ensuring the promotion of customer focus throughout the organization;
e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are implemented.

5 Planning

6.1 Action to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in **4.1** and the requirement referred to in **4.2** and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result (s):

b) enhance desirable effects;

c) achieve improvement,

6.1.2 The organization shall plan:

a) action to address these risks and opportunities;

b) how to:

1) integrate and implement the action into its quality management system processes (see **4.4**)

2) evaluate the effectiveness of these actions.

Action taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Option to address risks ca include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customer's needs.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant function, levels and processes need for the quality management system.

The quality objectives shall:

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;

g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) when it will be responsible;

d) when it will be completed;

e) how the result will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see **4.4**)

The organization shall consider:

a) the purpose of the changes and their potential consequences;
b) the integrity of the quality management system;
c) the availability of resources;
d) the allocation or reallocation of responsibilities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

a) the capabilities of, and constraints on existing internal resources;
b) what needs to be obtained from external providers;

7.1.2 People

The organization shall determine and person necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its process and to achieve conformity of products and services.

NOTE Infrastructure can include:

a) building and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

These factors can differ substantially depending on the on the products and services provided

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable result when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources providing:

a) are suitable for specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
b) identified in order to determine their status;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organization knowledge

The organization shall determine the knowledge for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organization knowledge is knowledge specific to the organization: it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organization knowledge can be based on:

a) internal sources (e.g. Intellectual property: knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the result of improvements in processes, products and services):

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
b) ensure that these person are competent on the basis of appropriate education, training, or experience;
c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the action taken;
d) retain appropriate documented information as evidence of competence.

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

7.3 Awareness

The organization shall ensure that person doing work under the organization's control are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system. Including the benefits of improved performance;

d) the implications of not conforming with the quality management system requirements.

7.4 communication

The organization shall determine the internal and external communication relevant to the quality management system, including:

a) on what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;

e) who communicate;

7.5 Documented information

7.5.1 General

The organization's quality management system shall:

a) documented information required by this International Standards;

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

The organization's quality management system shall include:

a) documented information required by this International Standards;

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes

— the complexity of processes and their interactions;

— the competence of person.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date author, or reference number):

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this International Standards shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control):

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Document information of retained of conformity shall be protected from unintended alterations.

NOTE access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the process (see **4.4**) needed to meet the requirements for the provision of products and services, and to implement the determinted in **clause 6** , by:

a) determining the requirements for the products and services;

b) establishing criteria for:

1) the processes;

2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the process in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary;

1) to have confidence that the processes have been carried out as planned;

2) to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operation.

The organization shall control planed changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see **8.4**)

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency action, when requirement for contingency action, when relevant.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:

1) any application statutory and regulatory requirements;

2) those considered necessary by the organization;

b) the organization can meet the claims for the production and services it offers.

8.2.3 Review of the requirements for products and services

8.2.3.1 The organization shall ensure that it has ability to meet the requirements for products and services to be offered customer. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for the specified or intended use, when know;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE in some situation, such as internet sales, a formal review is impractical for each order, instead, the review can cover relevant product information, such as catalogues.

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and service

The organization shall ensure that relevant documented information is amended, and that relevant person are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

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

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need control interfaces between person involved in the design and development process;

g) the need for involvement of customers and user in the design and development process;

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) Functional and performance requirements;

b) information derived previous design and development activities;

c) standards or codes of practice that the organization has committed to implement;

e) potential consequences of failure due to the nature of the products and services.

Input shall be adequate for design and development purpose, complete and unambiguous.

Conflicting design shall retain document information on design and development inputs.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that

a) the result to be achieved are defined;

b) review are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary action are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs

a) meet the input requirements;

b) are adequate for the subsequent process for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;

b) the result development changes;

c) the authorization of the changes;

d) the action taken to prevent adverse impacts.

8.4 Control of externally provided, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided process, products and services when:

a) products and services from external providing are intended for incorporation into the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is providing by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary action arising from the evaluations.

8.4.2 Type and extent of control

The organization shall ensure that external provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided process remain within the control of its quality management system;

b) define both the controls that it intends to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided process, products and services meet requirements.

8.4.3 Information for external providers

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

C) competence, including any qualification of person;

d) control and monitoring of the external provider's performance to be applied by the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization or its customer, intends to perform at the external providers' premises.

8.5 production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the result to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent person, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned result of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of action to human error;

h) the implementation of release, delivery and post-delivery activities.

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external providers is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to be customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider;

a) statutory and regulatory requirements;

b) the potential undesired consequence associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback.

NOTE post-delivery activities can include action under warranty provisions, contractual obligation such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary action from the review.

8.6 Release of products and services

The organization shall implements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and , as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

8.7 Control of nonconforming outputs

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person (s) authorizing the delivery.

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways;

a) correction;

b) segregation, containment ,return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the action taken;

c) describes any concession obtained;

d) identifies the authority deciding the action in respect of the nonconformity.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1 General

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid result;

c) when the monitoring and measuring shall be performed;

d) when the result from monitoring and measurement shall be analysed and evaluated.

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

The organization shall retain appropriate documented information of the results.

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of action taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statical techniques.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planed intervals to provide information on whether the quality management system;

a) conforms to:

1) the organization's own requirements for its quality management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2 The organization shall;

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the result of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the result of the audits are reported to relevant management;

e) take appropriate correction and action without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit result.

NOTE See ISO 190011 for guidance.

9.3 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and aligment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and Internal Issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective action;

5) monitoring and measurement results;

6) audit results;

7) the performance of external providers;

d) the adequacy of resources;

e) the effectiveness of action taken to address risk and opportunities (see 6.1)

f) opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review shall include decisions and action related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

The organization shall retain documented information as evidence of the result of management reviews.

10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary action to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improvement products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity;

2) determining the cause of the nonconformity;

3) determining If similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

Corrective action shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the result of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.