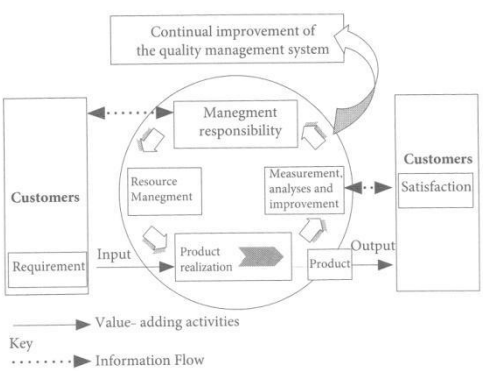
**Foreword**

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 Electro technical Commission (IEC) on all matters of electro technical standardization. International Standards are drafted in accordance with the rules given in the ISOIIEC Directives, Part2.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 7 5 % of the member bodies casting a vote.
Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held

responsible for identifying any or all such patent rights.
ISO 9001 was prepared by Technical Committee ISO/TC 17 6, Quality management and quality assurance Subcommittee SC 2, Quality systems.
This fourth edition cancers and replaces the third edition(ISo9001:2000),which has been amended to clarify points in the text and to enhance compatibility with lSO1400l:2004.
Details of the changes between the third edition and this fourth edition are given in Annex B.

**Introduction**

**0. 1 General**

The adoption of a quality management system should be a strategic decision of an organization The design and implementation of an organization's quality management system is influenced by

a) Its organizational environment, changes in that environment, and the risks associated with that environment,

b) Its varying needs,

c) Its particular objectives,

d) The products it provides,

e) The processes it employs,

f) Its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirement for products. Information marked 'NOTE" is for guidance in understanding g or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's

ability to meet customer, statutory and regulatory requirements applicable to the product, and the organizations own requirements.
The quality management principles stated in ISO and ISO 9004 have been taken into consideration dourine be development of this International Standard.

**0.2 Process approach**

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 requirement.
For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.
The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "Process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.
When used within a quality management system, such an approach emphasizes the importance of
a) Understanding and meeting requirements,
b) The need to consider processes in terms of added value,
c) Obtaining results of process performance and effectiveness, and
d) Continual improvement of processes based on objective measurement.
The model of a process-based quality management system shown in figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology know as "Plan-Do-Check-Act" (PDCA) can be applied to all processes.
PDCA can be briefly described as follows.
Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.
Do: implement the processes.
Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
Act: take actions to continually improve process performance.

**Figure 1 - Model of a process-based quality management system**

**0.3 Relationship with ISO 9004**

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other but can also be used independently.

ISO 9001 specifies requirement for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management System in meeting customer requirements.

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained Success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; It addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

**0.4 Compatibility with other management systems**

During the development of this International Standard, due consideration was given to the provisions of ISO14001:2004to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO14001:2004.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

**Quality management systems - Requiremen6**

## 1 Scope

### 1.1 General

This International Standard specifies requirements for a quality management system where an organization
a) Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
b) Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
NOTE 1 In this Interactional Standard, the term "product" only applies to
a) Product intended for, or required by, u customer,
b) Any intended output resulting from the product realization processes.
NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

### 1.2 Application

A1l requirements of this International Standard are generic and are intended to be applicable to

all organizations, regardless of type, size and product provided.
Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7 , and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

**2 Normative references**
The following referenced documents are indispensable for the application of this document. 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 Fundament al s and vocabulary

**3 Terms and definitions**
For the purposes of this document, the terms and definitions given in ISO 9000 apply.

Throughout the text of this International Standard, wherever the term "product "occurs, it can also mean "service'"

**4 Quality management system**

**4.1 General requirements**

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard'

The organization shall

a) Determine the processes needed for the quality management system and their application throughout the organization (see 1 .2),

b) Determine the sequence and interaction of these processes,

c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) Monitor, measure where applicable, and analyze these processes, and

f) Implement actions necessary to achieve planned results and continual improvement of these processes.
These processes shall be managed by the organization in accordance with the requirements of this International Standard.
Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes.
The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.
NOTE L processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement'
NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external Party.
NOTE 3 Ensuring control over outsourced process does not absolve the organization of the responsibility' of conformity to all customer, statutory and regulatory requirements.

The type and extent of control to be applied to the outsourced process can be influenced by factors such as:
a) The potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
b) The degree to which the control for the process is shared"
c) The capability of achieving the necessary control through the application of 7 .4.

**4 .2 Documentation requirements**

**4.2.1 General**

The quality management system documentation shall include
a) Documented statements of a quality policy and quality' objectives,
b) A quality manual,
c) Documented procedures and records required by this International Standard, and
d) Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.
NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and

maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.
NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to
a) The size of organization and type of activities,
b) The complexity of processes and their interactions, and
c) The competence of Personnel.
NOTE 3 The documentation can be in any form or type of medium.

**4.2.2 Qualify manual**
The organization shall establish and maintain a quality manual that includes
a) The scope of the quality management system, including details of and justification for any exclusions (see 1.2),
b) The documented procedures established for the quality management system, or reference to them, and
c) A description of the interaction between the processes of the quality management system.

**4.2.3 Control of documents**

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4-2.4.

A documented procedure shall be established to define the controls needed

a) To approve documents for adequacy prior to issue,

b) To review and update as necessary and re-approve documents,

c) To ensure that changes and the current revision s13n6 of documents are identified,

d) To ensure that relevant versions of applicable documents are available at points of use,

e) To ensure that documents remain legible and readily identifiable,

f) To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any Purpose.

**4.2.4 Control of records**

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.
The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.
Records shall remain legible, readily identifiable and retrievable.

**5 Management responsibility**

**5. 1 Management commitment**

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by
a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) Establishing the quality policy'
c) Ensuring that quality objectives are established,
d) Conducting management reviews, and
e) Ensuring the availability of resources.

**5.2 Customer focus**
Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 5.2.1).

**5.3 Quality policy**
Top management shall ensure that the quality policy
a) Is appropriate to the purpose of the organization,
b) Includes a commitment to comply with requirement and continually improve the effectiveness of the quality management system,
c) Provides a framework for establishing and reviewing quality objectives,
d) Is communicated and understood within the organization and
e) Is reviewed for continuing suitability.

**5.4 Planning**
**5 .4.1 Quality objectives**
Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7 .1 a)], are established at relevant functions and levels within the organization. The quality objectives

shall be measurable and consistent with the quality policy.

**5.4.2 Qualify management system planning**
Top management shall ensure that
a) The planning of the quality management system is, carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

**5.5 Responsibility, authority and communication**
**5.5. 1 Responsibility and authority**
Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

**5 .5 .2 Management representative**
Top management shall appoint a member of the organization's management who, irrespective of other responsibilities' shall have responsibility and authority that includes

a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
b) Reporting to top management on the performance of the quality management system and any need for improvement, and
c) Ensuring the promotion of awareness of customer requirements throughout the organization.
NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

**5.5.3 Internal communication**
Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

**5.6 Management review**
**5.6.1 General**
Top management shall review the organization's quality management system, &t planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for

improvement and the need for changes to the quality management system. including the quality policy and quality objectives.
Records from management reviews shall be maintained (see 4.2.4).

**5.6.2 Review input**
The input to management review shall include information on
a)Results of audits,
b)Customer feedback,
c)Process performance and product conformity,
d) Status of preventive and corrective actions,
e)Follow-up actions from previous management reviews,
f)Changes that could affect the quality management system, and
g)Recommendations for improvement.

**5.6.3 Review output**
The output from the management review shall include any decisions and actions related to
a) Improvement of the effectiveness of the quality management system and its processes,
b) Improvement of product related to customer requirements, and
c) Resource needs.

**6 Resource management**

**6.1 Provision of resources**

The organization shall determine and provide the resources needed

a) To implement and maintain the quality management system and continually improve its effectiveness, and

b) To enhance customer satisfaction by meeting customer requirements.

**6.2 Human resource**

**6.2.1 General**

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

**6.2.2 Competence, training and awareness**

The organization shall

a)Determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) Where applicable, provide training or take other actions to achieve the necessary competence,
c) Evaluate the effectiveness of the actions taken,
d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the qualify objectives, and
e) Maintain appropriate records of education, training skills and experience (see 4.2.4).

**6.3 Infrastructure**
The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,
a) Buildings, workspace and associated utilities,
b) Process equipment (both hardware and software), and
c) Supporting services (such as transport, communication or information systems).

**6.4 Work environment**
The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

## 7 Product realization

### 7.1 Planning of product realization

The organization shall be plan and develop the process needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1)

In planning product realization, the organization shall determine the following, as appropriate:

a) Quality objectives and requirements for the product.

b) The need to establish processes and documents, and to provide resources specific to the product;

c) Required verification, validation, monitoring. measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
The output of this planning shall be in a form suitable for the organization's method of operations.
NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.
NOTE 2 The organization may also apply the requirements given in7.3 to development of product realization processes

**7 .2 Customer-related processes**
**7 .2.1 Determination of requirements related to the product**
The organization shall determine
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 specified or intended use, where known,
c) Statutory and regulatory requirements applicable to the product, and

d) Any additional requirements considered necessary by the organization.
NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

**7.2.2 Review of requirements related to the product**
The organization shall review the requirements related to the product. The review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that
a) Product requirement are defined,
b) Contract or order requirements differing from those previously expressed are resolved, and
c) The organization has the ability to meet the defined requirements.
Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the su3tomer requirements shall be confirmed by the organization before acceptance.
Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

**7 .2.3 Customer communication**
The organization shall determine and implement effective arrangements for communicating with customers in relation to
a) Product information,
b) Enquiries, contracts or order handling, including amendments, and
c)Customer feedback, including customer complaints.

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**7.3 Design and development**

**7.3.1 Design and development planning**

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) The design and development stages,

b) The review, verification and validation that are appropriate to each design and development stage, and,

c) The responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design, and development progresses.

NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

**7.3.2 Design and development inputs**

Inputs relating to product requirements, shall be determined and records maintained (see4.2.4) .
These inputs shall include
a) Functional and performance requirements,
b) Applicable statutory and regulatory requirements,
c) Where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development.
The inputs shall be reviewed for adequacy.
Requirements shall be complete, unambiguous and not in conflict with each other.

**7.3.3 Design and development outputs**

The outputs of design and developments shall be in a form suitable for verification against the design and development input and shall be approved prior to release.
Design and development outputs shall
a) Meet the input requirements for Design and development
b) Provide appropriate information for purchasing, production and service provision,
c) Contain or reference product acceptance criteria, and

d) Specify the characteristics of the product that are essential for its safe and proper use.
NOTE: Information for production and service provision can include details for the preservation of product.

**7.3.4 Design and development review**
At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see7.3.1)
a) To evaluate the ability of the results of Design and development to meet requirements, and
b) To identify any problems and propose necessary actions.
Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4)

**7.3.5 Design and development verification**
Verification shall be performed in accordance with planed arrangements (see7.3.1) to ensure that the design and development outputs have met the design and development input

requirements. Records of the results of the verification and any necessary actions shall be maintained (see4.2.4)

**7.3.6 Design and development validation**

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

**7.3.7 Control of design and development changes**

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any

necessary actions shall be maintained (see 4.2.4).

**7.4 Purchasing**

**7.4.1 Purchasing process**

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluation and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

**7.4.2 Purchasing information**

Purchasing information shall describe the product to be purchased, including, where appropriate,

a) Requirements for approval of product, procedures, processes and equipment,

b) Requirements for qualification of personnel, and
c) Quality management system requirements.
The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

**7.4.3 Verification of purchased product**
The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

**7 .5 Production and service provision**
**7.5.1 Control of production and service provision**
The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

a) The availability of information that describes the characteristics of the product,
b) The availability of work instructions, as necessary
c) The use of suitable equipment,
d) The availability and use of monitoring and measuring equipment,
e) The implementation of monitoring and measurement, and
f) The implementation of product release, delivery and post-delivery activities.

**7 .5.2 Validation of processes for production and service provision**

The or generation shall I validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
Validation shall demonstrate the ability of these processes to achieve planned results.
The organization shall establish arrangements for these processes including, as applicable,
a) Defined criteria for review and approval of the processes,

b) Approval of equipment and qualification of personnel,
c) Use of specific methods and procedures,
d) Requirements for records (see 4.2.4), and
e) Revalidation.

**7 .5.3 identification and traceability**

Where appropriate, the organization shall identify' the product by suitable means throughout product realization.
The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.
Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).
NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

**7 .5.4 Customer Properly**

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.2).
NOTE Customer property can include intellectual property and personal data.

**7.5.5 Preservation of product**
The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements.
As applicable, preservation shall include identification, handling, packaging, storage and protection.
Preservation shall also apply to the constituent parts of a product.

**7.6 Control of monitoring and measuring equipment**
The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
Where necessary to ensure valid results, measuring equipment shall
a) Be calibrated or verified, or both, at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
b) Be adjusted or re-adjusted as necessary;
c) Have identification in order to determine its calibration status;
d) Be safeguarded from adjustments that would invalidate the measurement result;
e) Be protected from damage and deterioration during handling, maintenance and storage.
In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.
Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.
NOTE confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

## 8 Measurement, analysis and improvement

### 8.1 General

The organization shall plan and implement the monitoring measurement, analysis and improvement processes needed
a) To demonstrate conformity to product requirements.
b) To ensure conformity of the quality management system, and
c) To continually improve the effectiveness of the quality management system.
This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

**8.2 Monitoring and measurement**

**8.2.1 Customer satisfaction**

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements.

The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments. Warranty claims and dealer reports.

**8.2.2 Internal audit**

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) Conforms to the planned managements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) Is effectively implemented and maintained

An audit program shall be planned taking into consideration the status and importance of the

processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
Records of the audits and their results shall be maintained (see 4.2.4).
The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).
NOTE See ISO 19011 for guidance.

**8.2.3 Monitoring and measurement of processes**
The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system

processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved correction and corrective action shall be taken, as appropriate.
NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

**8.2.4 Monitoring and measurement of product**
The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the Product realization process in accordance with the planned arrangements (see 7.1).Evidence of conformity with the acceptance criteria shall be maintained.
Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).
The release of product and delivery of service to the customer shall not proceed until the

planned arrangements (see 7.I) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

**8.3 Control of nonconforming product**

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product' Where applicable, the organization shall deal with non-conforming product by one or more of the following ways:

a) By taking action to eliminate the detected nonconformity:

b) By authorizing its use; release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) By taking action to preclude its original intended use or application;

d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

**8.4 Analysis of data**
The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.
The analysis of data shall provide information relating to
a) Customer satisfaction (see 8.2.1),
b) Conformity to product requirement (see 8.2.4),
c) Characteristics and trends of processes and products. including opportunities for preventive action (see 8.2.3 and 8.2.4), and
d) Suppliers (see 7 .4).

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**8.5 Improvement**

**8.5.1 Continual improvement**

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

**8.5 .2 Corrective action**

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence.

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

A documented procedure shall be established to define requirements for

a) Reviewing nonconformities (including customer complaints),

b) Determining the causes of nonconformities,

c) Evaluating the need for action to ensure that nonconformities do not recur,

d) Determining and implementing action needed,

e) Records of the results of action taken (see 4.2.4), and

f) Reviewing the effectiveness of the corrective action taken.

**8.5.3 Preventive action**

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) Determining potential nonconformities and their causes,

b) Evaluating the need for action to prevent occurrence of nonconformities,

c) Determining and implementing action needed,

d) Records of results of action taken (see 4.2.4), and

e) Reviewing the effectiveness of the preventive action taken

**Annex A**
(Informative)
Correspondence between ISO 9001:2008 and ISO 14001:2004
**Table A.1**
Correspondence between ISO 9001:2008 and ISO 14001:2004

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1<br>0.2 | | Introduction |
| General | 0.3 | | |
| Process approach | 0.34 | | |
| Relationship with ISO 9004 | | | |
| Compatibility with other management systems | | | |
| Scope (title only) General | 1<br>1.1 | 1 | scope |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

**Table A.2**
Correspondence between ISO 14001:2004 and ISO 9001:2008

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| | 0.2 | | |
| General | 0.3 | | |
| Process approach | 0.34 | | |
| Relationship with ISO 9004 | | | |
| Compatibility with other management systems | | | |
| Scope (title only) General | 1<br>1.1 | 1 | scope |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2 | Legal and other requirements |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
| General requirements | 4.1 | 4.1 | General requirements |
| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | 4.2<br>4.4.1 | Environmental policy<br>Resources, roles, responsibility and authority |
| Customer focus | 5.2 | 4.3.1 | Environmental aspects |
| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

| ISO 9001:2008 | | ISO 14001:2004 | |
|---|---|---|---|
| Introduction (title only) | 0.1 | | Introduction |
| General | 0.2 | | |
| Process approach | 0.3 | | |
| Relationship with ISO 9004 | 0.34 | | |
| Compatibility with other management systems | | | |
| Scope (title only) | 1 | 1 | scope |
| General | 1.1 | | |
| Application | 1.2 | | |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality management system (title only) | 4 | 4 | Environmental management system requirements (title only) |
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| Documentation requirements (title only) | 4.2 | | |
| General | 4.2.1 | 4.4.4 | Documentation |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | 4.4.5 | Control of documents |
| Control of records | 4.2.4 | 4.5.4 | Control of records |
| Management responsibility (title only) | 5 | | |
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| | | 4.3.2<br>4.6 | legal and other requirements<br>Management review |
| Quality policy | 5.3 | 4.2 | Environmental |

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