Foreword

Comments received on the Annex SL common text and High Level Structure will not be considered by WG 24 for the development of this Working Draft.

Any such comments that are received will be directed to ISO/TC 176/SC2/AHG 03 "Input into the JTCG" for consideration for forwarding to the JTCG during any future revision of Annex SL (for which there are no plans at this time).

Comments for additions to the Annex SL common text or High Level Structure will be considered, provided that the additional text does not contradict or undermine the intent of the Annex SL text.

Introduction

{Secretary: To be developed}

1 Scope

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 International Standard, the term “product” only applies to

a) product intended for, or required by, a customer,

b) any intended output resulting from the Operations processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal 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 — Fundamentals and vocabulary*

3 Terms and definitions

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

The Annex SL terms are currently incorporated to assist reviewers of the draft. At the moment there is no agreement to incorporate such terms in ISO 9001, and they will be removed later into ISO 9000. Any comments received on the terms and definitions will be forwarded for SC1 to review."

3.01

organization

*person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its **objectives** (3.08)*

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

3.02

interested party

*person or **organization** (3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity*

3.03

requirement

need or expectation that is stated, generally implied or obligatory

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

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

3.04

management system

*set of interrelated or interacting elements of an **organization** (3.01) to establish **policies** (3.07) and **objectives** (3.08) and **processes** (3.12) to achieve those objectives*

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning, operation, etc.

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

3.05

top management

*person or group of people who directs and controls an **organization** (3.01) at the highest level*

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

*Note 2 to entry: If the scope of the **management system** (3.04) covers only part of an organization then top management refers to those who direct and control that part of the organization.*

3.06

effectiveness

extent to which planned activities are realized and planned results achieved

3.07

policy

*intentions and direction of an **organization** (3.01) as formally expressed by its **top management** (3.05)*

3.08

objective

result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

*Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and **process** (3.12)). An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective or by the use of other words with similar meaning (e.g. aim, goal, or target).*

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

Note 4 to entry: In the context of quality management systems standards quality objectives are set by the organization, consistent with the quality policy, to achieve specific results.

3.09

risk

effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of efficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

*Note 3 to entry: Risk is often characterized by reference to potential **events** (ISO Guide 73, 3.5.1.3) and **consequences** (ISO Guide 73, 3.6.1.3), or a combination of these.*

*Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated **likelihood** (ISO Guide 73, 3.6.1.1) of occurrence.*

3.10

competence

ability to apply knowledge and skills to achieve intended results

3.11

documented information

*information required to be controlled and maintained by an **organization** (3.01) and the medium on which it is contained*

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to

*– the **management system** (3.04), including related **processes** (3.12);*

– information created in order for the organization to operate (documentation);

– evidence of results achieved (records).

3.12

process

set of interrelated or interacting activities which transforms inputs into outputs

3.13

performance

measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

*Note 2 to entry: Performance can relate to the management of activities, **processes** (3.12), products (including services), systems or **organizations** (3.01).*

3.14

***outsource** (verb)*

*make an arrangement where an external **organization** (3.01) performs part of an organization's function or **process** (3.12)*

*Note 1 to entry: An external organization is outside the scope of the **management system** (3.04), although the outsourced function or process is within the scope.*

3.15

monitoring

*determining the status of a system, a **process** (3.12) or an activity*

Note 1 to entry: To determine the status there may be a need to check, supervise or critically observe.

3.16

measurement

***process** (3.12) to determine a value*

3.17

audit

*systematic, independent and documented **process** (3.12) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled*

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

3.18

conformity

*fulfilment of a **requirement** (3.03)*

3.19

nonconformity

*non-fulfilment of a **requirement** (3.03)*

3.20

correction

*action to eliminate a detected **nonconformity** (3.19)*

3.21

corrective action

*action to eliminate the cause of a **nonconformity** (3.19) and to prevent recurrence*

3.22

continual improvement

recurring activity to enhance ***performance*** *(3.13)*

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 that affect its ability to achieve the intended outcome(s) of its quality management system.

The organization shall take into account these issues for determining risks and opportunities referred to in 6.1.

NOTE 1 Understanding the organization's external context can include, but is not limited to:

a) the social and cultural, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;
b) key drivers and trends which can have an impact on the objectives of the organization; including customers changing needs;
c) relationships with, and perceptions, values and expectations of, external interested parties.

NOTE 2 Understanding the organization's internal context can include, but is not limited to:

a) governance, organizational structure, roles and accountabilities;
b) policies, objectives and the strategies that are in place to achieve them;
c) capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies);
d) information systems, information flows and decision making processes (both formal and informal);
e) relationships with, and perceptions and values of, internal stakeholders and the organization's culture;
f) standards, guidelines and models adopted by the organization;
g) the form and extent of contractual relationships.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine

- *the interested parties that are relevant to the quality management system, and*
- *the quality management system related requirements, of these interested parties.*

NOTE 1 Typical examples of relevant interested parties could be:

a) Direct customers, end users;
b) suppliers, distributers, retailers, partners, competitors,

c) shareholders,
d) employees and labour unions
e) society, including regulators.

NOTE 2 Customer and other interested parties needs and expectations can include consideration of innovation opportunities.

NOTE 3 Customer and other interested parties needs and expectations can include consideration of other requirements than quality related, such as requirements related to sustainability, social and environmental issues.

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

- *the external and internal issues referred to in 4.1, and*
- *the requirements referred to in 4.2.*
- that all requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

When defining the scope, the organization shall document and justify any decision not to apply any requirement of this International Standard and to exclude it from the scope of the quality management system. Any such exclusion shall not affect the organization's ability or responsibility to provide conforming product that meets the quality management system requirements referred to in 4.2.

Where an organization chooses to outsource any process that affects product conformity to requirements, these processes shall be included within the established scope of the quality management system.

The scope and any exclusions *shall be available as documented information* and shall be made available to interested parties on request.

NOTE The scope of the QMS may include the whole of the organization, specific functions of the organization, specific sections of the organization, or one or more functions across a group of organizations, provided it does not affect the organization's ability and responsibility to provide conforming product that meet the QMS requirements referred to in 4.2.

4.4 Quality management system

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, 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, taking into account 4.1 to 4.3,
b) determine the inputs required and the outputs expected from each process,
c) determine the sequence and interaction of these processes,
d) determine the risks to quality performance if unintended outputs are produced or process interaction is ineffective,
e) determine criteria, methods and measurements needed to ensure that both the operation and control of these processes are effective,
f) ensure the availability of resources referred to in 7,
g) allocate responsibilities and authorities for particular processes or sets of processes.
h) monitor, analyse and review these processes,
i) implement actions necessary to achieve planned results and continual improvement of these processes. and
j) ensure that new or revised processes continue to deliver the intended outcomes.

5 Leadership

5.1 Leadership and commitment

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

- *ensuring that policies and objectives are established for the quality management system and are compatible with the strategic direction of the organization* based on the Quality Management Principles
- *ensuring the integration of the quality management system requirements into the organization's business processes*
- *ensuring that the resources needed for the quality management system are available*
- *communicating the importance of effective quality management and of conforming to the quality management system requirements* as well as statutory and regulatory requirements
- *ensuring that the quality management system* and its processes *achieve its intended outcome(s)*
- ensuring that the risks which could affect the meeting of applicable product requirements are identified, assessed and managed
- involving*, directing and supporting persons to contribute to the effectiveness of the quality management system*

- ensuring that customer requirements are determined and are met with the aim of enhancing customer satisfaction
- *promoting continual improvement*
- *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility*
- ensuring the quality policy referred to in 5.2 is understood and followed within the organization

NOTE Reference to "business" in this International Standard should be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Policy

Top management shall establish a quality policy that

- *is appropriate to the purpose of the organization* and its intended outcome*;*
- *provides a framework for setting quality objectives;*
- *includes a commitment to satisfy applicable requirements, and*
- *includes a commitment to continual improvement of the quality management system.*

The quality policy shall

- *be available as documented information*
- *be communicated within the organization*
- *be available to interested parties, as appropriate.*
- be reviewed for continuing suitability

NOTE The quality policy should not contradict the Quality Management Principles

5.3 Organizational roles, responsibilities and authorities

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

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International Standard ~~and~~,

b) reporting on the performance of the quality management system to top management and any need for improvement,

c) ensuring the promotion of awareness of customer requirements throughout the organization, and

d) ensuring that the processes are delivering the required outputs and that the interactions between processes are producing the required quality management system outcomes

6 Planning

6.1 Actions to address risks and opportunities

When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities related to product conformity and customer satisfaction *that need to be addressed to*

- *assure the quality management system can achieve its intended outcome(s)*
- *prevent, or reduce, undesired effects*
- *achieve continual improvement.*

The organization shall plan:

a) actions to address these risks and opportunities and

b) how to

- *integrate and implement the actions into its quality management system processes* (see 4.4)
- *evaluate the effectiveness of these actions*

The organization shall ensure that the need to consistently provide product that meets customer requirements and enhance customer satisfaction is a deciding factor when determining actions to address risks, e.g. when choosing between options such as risk avoidance, risk mitigation or risk acceptance

6.2 Quality objectives and planning to achieve them

The organization shall establish quality objectives at relevant functions and levels and in accordance with its overall business objectives and product conformity and customer satisfaction.

The quality objectives shall

- *be consistent with the quality policy*
- *be measurable (if practicable)*
- *take into account applicable requirements*
- *be monitored*
- *be communicated, and*
- *be updated as appropriate*

Quality objectives that impact on product conformity or customer satisfaction shall be implementedin a timely and effective manner**.**

The organization shall retain documented information on the quality objectives.

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

- *what will be done*
- *what resources will be required (see 7.1)*
- *who will be responsible*
- *when it will be completed*
- *how the results will be evaluated.*

6.3 Planning and control of changes

The organisation shall undertake change in a planned and systematic manner, reviewing the potential consequences of changes and taking action as necessary, to ensure the integrity of the quality management system is maintained.

The organization shall ensure that changes to product, infrastructure, quality management system processes, documented information or other changes arising from considerations as part of management review are assessed for suitability and approved prior to implementation. The assessment shall include

a) identification of risks and risk control measures associated with the change,
b) consequences for resource needs,
c) any necessary verification or validation, and
d) confirmation that the desired effect has been achieved without adverse effects to product conformity.

Personnel authorized to approve changes shall be identified.

Documented information describing the results of the review of changes and any necessary actions shall be maintained. (see 7.5)

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 to enhance customer satisfaction by meeting customer requirements.

In determining the resource requirements the organisation shall consider

- current in-house capabilities and limitations

- which process or product needs can be supported with existing resource
- which process or product needs require additional or changed resource that is to be deployed under the organisations own direct control
- which process or product needs are to be satisfied by outsourcing to an external party.

The organisation shall ensure that the introduction of any new or additional resource to be deployed under its direct control shall be subject to change management in accordance with the requirements of Clause 6.3 – Planning and control of changes (see 6.3)

The organization shall establish, implement and maintain the controls needed temporarily or permanently to utilize external parties. The type and extent of control to be applied to outsourced processes or product shall be defined within the quality management system.

The organization shall ensure that externally provided processes or product conform to specified requirements.

NOTE 1 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 2 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all requirements for the product that is delivered to its customers

NOTE 3 Consideration of support and resource requirements can include the necessary infrastructure, equipment, resources & compentence as well as the necessary financial supports in order to meet Quality objectives.

7.1.2 Infrastructure and work environment

The organization shall determine and provide the infrastructure and work environment needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software),
c) supporting services (such as transport, communication or information systems).

The infrastructure shall be maintained.

NOTE 1 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).

NOTE 2 Where it impacts on product or service quality, the organization needs to consider those who are working remotely, irrespective of where the work is done there should be controls in place

NOTE 3 Similar controls need to be considered for outsourcing

7.1.3 Monitoring and measuring instruments

The organisation shall ensure the availability of the monitoring and measuring instruments needed to verify conformity to product requirements and shall ensure that it is controlled and maintained fit for purpose.

Where necessary to ensure valid results, measuring instruments shall

a) be verified 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 ;
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 instrument is found not to conform to requirements. The organization shall take appropriate action on the instruments and any product affected.

Documented information of the results of calibration and verification shall be maintained.

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

7.1.4 Knowledge requirements

The organization shall determine, provide and maintain the knowledge resources needed to consistently provide product that meets customer needs and expectations and enhance customer satisfaction.This shall include consideration of the knowledge resources to respond to changing business environments referred to in 4.1, changing customer and interested party needs and expectations referred to in 4.2 and, where applicable, related innovation and improvement initiatives.

7.2 Competence

The organization shall:

- determine the competence requirements associated with each process or set of processes
- *determine the necessary competence of person(s) doing work under its control that affects its quality performance, and*
- *ensure that these persons are competent on the basis of appropriate education, training, or experience;*
- *where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, and*
- *retain appropriate documented information as evidence of competence*

NOTE1 Applicable actions may include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

NOTE 2 A gap analysis could be a useful tool for determining competences

7.3 Awareness

Persons doing work under the organization's control shall be aware of

- *the quality policy*
- *their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance*
- *the implications of not conforming with the quality management system requirements*

7.4 Communication

The organization shall determine the need for internal and external communications relevant to the quality management system including

- on what it will communicate
- when to communicate
- with whom to communicate

7.5 Documented information

7.5.1 General

The organization's quality management system shall include

- documented information required by this International Standard
- documented information determined by the organization as being necessary for the effectiveness of the quality management system.
- a description of the interaction between the processes 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, products and services,*
- *the complexity of processes and their interactions, and*
- *the competence of persons.*

7.5.2 Creating and updating

When creating and updating documented information the organization shall ensure appropriate

- *identification and description (e.g. a title, date, author, or reference number)*
- *format (e.g. language, software version, graphics) and media (e.g. paper, electronic)*
- *review and approval for suitability and adequacy.*

7.5.3 Control of documented Information

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

- *it is available and suitable for use, where and when it is needed*
- *it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).*

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

- *distribution, access, retrieval and use,*
- *storage and preservation, including preservation of legibility*
- *control of changes (e.g. version control)*
- *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 controlled.

NOTE Access implies a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information, etc.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1, by

- *establishing criteria for the processes*
- *implementing control of the processes in accordance with the criteria*
- *keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.*

The organization shall control planned 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 Interactions with customers and other interested parties

8.2.1 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, including risks and risk controls

d) requirements that are related to the product arising from other relevant interested parties referred to in 4.2, and

e) any additional requirements considered necessary by the organization.

8.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This 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 requirements 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

Documented information describing the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documented information is 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.

8.2.3 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,
c) customer feedback, including customer complaints (see 9.1)
d) expectations for handling customer property and
e) emergency and contingency needs

NOTE Customer property can include intellectual property and personal or confidential data.

8.3 Operational preparedness

In preparing for implementation, the organization shall determine the following, as appropriate,

a) quality objectives and requirements for the product;
b) risk identification, evaluation and control actions necessary on an ongoing basis
c) the need to establish processes and documented information,
d) the resources required arising from the requirements for the product;
e) the criteria for product acceptance;
f) required verification, validation, monitoring, measurement, inspection and test activities specific to the product;
g) documented information to be retained to provide evidence that processes and resulting product meet requirements; and
h) contingency plans, as applicable.

The output of this preparation shall be in a form suitable for the organization's method of operations.

NOTE 1 Documented information 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 in Design and Development to the development of processes for implementation.

8.4 Control of external processes or product

The type and extent of control applied to the external party and the externally-provided process or product shall be dependent upon

a) the risks identified
b) the potential impact of the provided processes or product on implementation activities or the organization's capability to provide product that conforms to requirements
c) the degree to which the control for the externally provided process is shared between the parties involved
d) the capability of achieving the necessary control through other means

The organization shall establish criteria for selection, evaluation and re-evaluation of external parties based on the risks and risk controls identified and their ability to provide processes or product in accordance with the organization's requirements. The organization shall evaluate and select external parties based on these criteria.

Documented information describing the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

Documented information shall be provided to the external party describing the product to be provided, including, where appropriate:

a) requirements for approval of product, procedures, processes or equipment,
b) requirements for competence of qualification of personnel, including necessary qualification,
c) quality management system requirements,
d) requirements for handling of supplier’s property provided to the organization, and
e) any activities that the organization intends to perform at the external party’s premises

The organization shall ensure the adequacy of specified requirements prior to their communication to the external party

NOTE Property belonging to external parties can include intellectual property and confidential or personal data.

8.5 Design and development

8.5.1 Define

The organization shall identify requirements of customers and other relevant interested parties and requirements related to the product referred to in 8.2.1. Inputs relating to product requirements shall be determined and documented information retained (see 7.5). These inputs shall include

a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) risks/hazards related to or arising from product
d) if applicable, information derived from previous similar designs, identified opportunities for improvement, or identified opportunities to innovate, including those from external sources, and
e) 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.

8.5.2 Analyze

The organization shall plan and control the design and development of product, including the process for planning and control of design and development changes.

The organization shall determine

a) the responsibilities and authorities for design and development
b) the design and development stages,
c) internal and external resource needs for design and development and subsequent operations arising from the identified product requirements, and
d) the review, verification and validation that are appropriate to each design and development stage.

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.

A systematic review shall be performed in accordance with planned arrangements

a) to evaluate the ability to meet requirements for the product,
b) to identify any problems and propose necessary actions, and
c) to evaluate design and development changes, including the effect of the changes on constituent parts and product already delivered.

Documented information describing the results of the review and any necessary actions shall be maintained (see 7.5).

NOTE Design and development verification and validation referred to in 8.5.4 have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

8.5.3 Implement

The organization shall implement the process for design and development and design and development changes. The outputs of the design and development process shall be in a form suitable for verification against the design and development input and shall be approved prior to release to operations.

Design and development outputs shall

a) meet the input requirements for design and development,
b) provide appropriate information for identification and control of external resources, implementation and product provision,
c) contain or reference product acceptance criteria, verification and validation methods and criteria,
d) identify risk control measures, and
e) 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.

A systematic review shall be performed in accordance with planned arrangements to

a) evaluate the ability of meet product requirements,
b) identify any problems and propose necessary actions, and
c) evaluate design and development changes, including the effect of the changes on constituent parts and product already delivered.

Documented information describing the results of the reviews and any necessary actions shall be maintained.

8.5.4 Verify and validate

Design and development verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Documented information describing the results of the verification and any necessary actions shall be maintained

Design and development validation shall be performed in accordance with planned arrangements referred to in 8.5.2 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.

Design and development changes shall be verified and validated, as appropriate, and approved before implementation.

Documented information describing the results of validation and any necessary actions shall be maintained.

8.5.5 Transfer to Operations

The organization shall ensure that design and development outputs identified during the design and development process ensure that they are suitable for operations before final approval.

8.6 Execution/Implementation

8.6.1 Control of production and service provision

The organization shall plan and implement 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,
f) the requirements for competence of personnel or their qualification, if necessary,
g) the implementation of product release, delivery and post-delivery activities, and
h) the implementation of risk controls.

8.6.2 Validation of processes for production and service provision

The organization shall 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 documented information, and

e) revalidation.

8.6.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout implementation

The organization shall identify the product status with respect to monitoring and measurement requirements throughout implementation.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain documented information.

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

8.6.4 Monitoring and measurement of product (see also 9.1)

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 implementation process in accordance with the planned arrangement. Evidence of conformity with the acceptance criteria shall be maintained.

The organization shall establish and implement the inspection or other activities necessary for ensuring that externally provided processes or product meet specified requirements.

Where the organization or its customer intends to perform verification at the external party's premises, the organization shall state the intended verification arrangements and method of product release in documented information provided to the external party.

Documented information shall indicate the person(s) authorizing release of product for delivery to the customer.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer

8.6.5 Control of nonconforming product (see also 10.1)

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery (see 10.1). Documented information shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

8.6.6 Property belonging to external parties

The organization shall exercise care with property belonging to external parties 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 external party's property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the external party and maintain documented information.

NOTE Property belonging to external parties can include intellectual property and confidential or personal data.

8.6.7 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.

8.6.8 Post delivery activities

The organization shall establish and implement processes to conduct necessary post delivery activities associated with the nature and intended lifetime of the product. The extent of post delivery activities that are required shall be established on the basis of risks associated with the product, customer feedback and statutory and regulatory requirements and shall include necessary actions when nonconforming product is detected after delivery or use has started

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.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine

- *what needs to be monitored and measured.* This shall include but not limited to
  a) conformity to product requirements,
  b) conformity of the quality management system,
  c) effectiveness of the quality management system and its processes,
  d) achievement of quality objectives and
  e) customer feedback / satisfaction
- *the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results*. This shall include determination of applicable
  a) monitoring and measuring instruments and
  b) statistical techniques, and the extent of their use.
- *when the monitoring and measuring shall be performed*
- *when the results from monitoring and measurement shall be analysed and evaluated.*
- what indicators of quality management system performance referred to in 9.3 d are necessary for reporting within the management review.

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.

The organization shall consider the type and extent of monitoring and/ or measurement in relation to risk encountered and on the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the quality performance and the effectiveness of the quality management system. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE Results of evaluation may generate opportunities for improvement.

9.1.2 Customer satisfaction

The organization shall monitor customer feedback to determine customer perceptions of the degree to which their requirements have been fullfilled.

The results of this monitoring shall include information related to

- the customer's needs and expectations
- the customer's views and perceptions of the organization, its processes and its products;

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

9.1.3 Analysis of data

The organization shall analyse appropriate data from monitoring, measurement and other relevant sources of information to

- demonstrate the suitability and effectiveness of the quality management system and
- evaluate where continual improvement of the effectiveness of the quality management system can be made.

The results of analysis and evaluation shall be used to prepare an input to the management review.

9.2 Internal Audit

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

a) conforms to
- *the organization's own requirements for its quality management system and*
- *the requirements of this International Standard;*

b) is effectively implemented and maintained.

The organization shall:

a) plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting. The audit programme(s) shall take into consideration the importance of the processes concerned, the related quality management system risks / opportunities, quality management system objectives *and the results 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 results of the audits are reported to relevant management, and

e) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.3 Management review

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. Management review shall be timely and relevant to operational outcomes.

The management review shall include consideration of

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system including any determined risks and opportunities;

c) information on the quality performance, including trends in:

- *nonconformities and corrective actions*
- *monitoring and measurement results, and*
- *audit results;*
- customer feedback,
- process performance and product conformity
- *opportunities for continual improvement.*

d) indicators **of** quality management system performance

The outputs of the management review shall include decisions related to continual improvement opportunities and, improvement of product related to customer requirements, resource needs *and any need for changes to the quality management system* including quality policy and quality objectives.

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

NOTE The management review can be integrated into the organisation's management meeting structure.

10 Improvement

10.1 Nonconformity and corrective action

When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable

- *take action to control and correct it, and*
- *deal with the consequences;*

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

- *reviewing the nonconformity*
- *determining the causes of the nonconformity, and*
- *determining if similar nonconformities exist, or could potentially occur;*
- *implement any action needed;*
- *review the effectiveness of any corrective action taken; and*
- *make changes to the quality management system, if necessary.*

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

The organization shall retain documented information as evidence of

- *the nature of the nonconformities and any subsequent actions taken, and*
- *the results of any corrective action.*

10.2 Continual improvement

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

The organisation shall define a structured approach for continual improvement of quality management system process and/or product through the use of the outcomes of performance evaluation (see 9).

The organisation shall maintain control over its processes in all areas of its quality management system during continual improvement implementation. Plans shall be established for change implementation to ensure consideration of the impact in all relevant areas.

NOTE Continual improvement may include processes /approaches such as innovation, lean, six sigma etc

Annex A

(informative)

{Secretary: To be developed, if required}

Bibliography

{Secretary: To be developed}