BRITISH STANDARD

BS EN 9100:2009

Aerospace series — Quality management systems — Requirements (based on ISO 9001:2000) and Quality systems — Model for quality assurance in design, development, production, installation and servicing (based on ISO 9001:1994)

ICS 03.120.10; 49.020

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Systèmes de management de la Qualité - Exigences des Organisations pour l'Aviation, l'Espace et la Défense

Qualitätsmanagementsysteme - Anforderungen an Organisationen der Luftfahrt, Raumfahrt und Verteidigung

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Foreword

This document (EN 9100:2009) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2010, and conflicting national standards shall be withdrawn at the latest by February 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 9100:2003.

This standard has been revised to incorporate the requirements of ISO 9001:2008. In addition, industry requirements, definitions and notes have been revised and additional requirements have been included in response to stakeholder needs.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from companies in the Americas, Asia/Pacific and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the aviation, space and defense industry, this standard can also be used in other industry sectors where a quality management system with additional requirements over an ISO 9001 system is needed.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

0 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 requirements for products. Information marked “NOTE” is for guidance in understanding 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 organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the 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 requirements.

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 known 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.

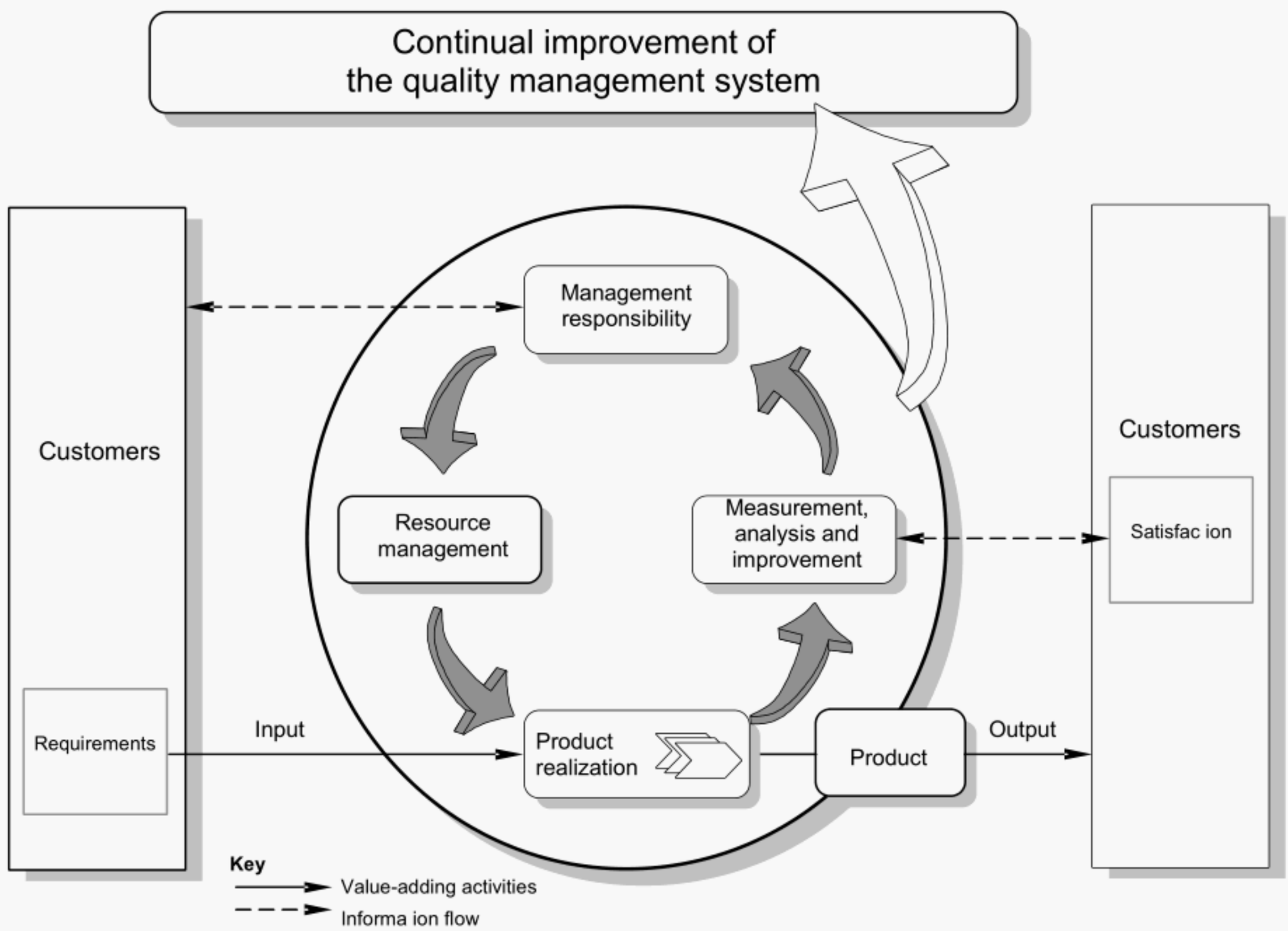

Figure 1 — Model of a process-based quality management system

QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

1 SCOPE

1.1 General

This standard includes ISO 9001:2008 [1] ***quality management system requirements and specifies additional aviation, space and defense industry requirements, definitions and notes as shown in bold, italic text.***

It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.

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 product realization processes.

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

1.2 Application

All 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.

This standard is intended for use by organizations that design, develop and/or produce aviation, space and defense products; and by organizations providing post-delivery support, including the provision of maintenance, spare parts or materials for their own products.

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1 *With the permission of the International Organization for Standardization (ISO). The complete standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.*

Organizations whose primary business is providing maintenance, repair and overhaul services for aviation commercial and military products; and original equipment manufacturers with maintenance, repair and overhaul operations that operate autonomously, or that are substantially different from their manufacturing/production operations; should use the IAQG-developed 9110 standard (see Bibliography).

Organizations that procure parts, materials and assemblies and resell these products to a customer in the aviation, space and defense industries, including organizations that procure products and split them into smaller quantities for resale, should use the IAQG-developed 9120 standard (see Bibliography).

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*

ISO 9001:2008, *Quality management systems — Requirements*

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2005 apply.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

3.1 *Risk*

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.2 *Special requirements*

Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry’s capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.3 *Critical items*

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.4 *Key characteristic*

An attribute or feature whose variation has a significant effect on product form, fit, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

NOTE Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

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's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

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 analyse 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 1 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 processes 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.

The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.

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 Quality 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 status 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.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

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 8.2.1).

Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.

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 requirements 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 Quality 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,

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

d) the organizational freedom and unrestricted access to top management to resolve quality management issues.

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, at 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 Ouput

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 Resources

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 quality 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 plan and develop the processes 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.

NOTE ***Quality objectives and requirements for the product include consideration of aspects such as***

- ***product and personal safety,***
- ***reliability, availability and maintainability,***
- ***producibility and inspectability,***
- ***suitability of parts and materials used in the product,***
- ***selection and development of embedded software, and***
- ***recycling or final disposal of the product at the end of its life.***

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)***;***

e) configuration management appropriate to the product;

f) resources to support the use and maintenance of the product.

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 in 7.3 to the development of product realization processes.

7.1.1 *Project Management*

As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 *Risk Management*

The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

a) assignment of responsibilities for risk management,

b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),

c) identification, assessment and communication of risks throughout product realization,

d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and

e) acceptance of risks remaining after implementation of mitigating actions.

7.1.3 Configuration Management

The organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product

a) configuration management planning,

b) configuration identification,

c) change control,

d) configuration status accounting, and

e) configuration audit.

NOTE See ISO 10007 for guidance.

7.1.4 Control of Work Transfers

The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.

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 Requirements related to the product can include special requirements.

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. 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,

c) the organization has the ability to meet the defined requirements***,***

d) special requirements of the product are determined, and

e) risks (e.g., new technology, short delivery time frame) have been identified (see 7.1.2).

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 customer 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.

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.

Where appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.

The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

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 (see 4.2.4). 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 development 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,

d) specify the characteristics of the product that are essential for its safe and proper use***, and***

e) specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.

The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example

— ***the drawings, part lists and specifications necessary to define the configuration and the design features of the product, and***

— ***the material, process, manufacturing and assembly data needed to ensure conformity of the product.***

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 (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements,

b) to identify any problems and propose necessary actions***, and***

c) to authorize progression to the next stage.

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 planned arrangements (see 7.3.1) 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 (see 4.2.4).

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).

7.3.6.1 Design and Development Verification and Validation Testing

Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following

a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria,

b) test procedures describe the method of operation, the performance of the test and the recording of the results,

c) the correct configuration of the product is submitted for the test,

d) the requirements of the test plan and the test procedures are observed, and

e) the acceptance criteria are met.

7.3.6.2 Design and Development Verification and Validation Documentation

At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

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).

Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3).

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 be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

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 evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

NOTE One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, organization approvals from government authorities). Use of such data would be only one component of an organization's supplier control process and the organization remains responsible for verifying that purchased product meets specified purchase requirements.

The organization shall

a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),

b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,

c) define the necessary actions to take when dealing with suppliers that do not meet requirements,

d) ensure where required that both the organization and all suppliers use customer-approved special process sources,

e) define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and

f) determine and manage the risk when selecting and using suppliers (see 7.1.2).

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,

c) quality management system requirements***,***

d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,

e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,

f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,

g) requirements regarding the need for the supplier to

- ***notify the organization of nonconforming product,***
- ***obtain organization approval for nonconforming product disposition,***
- ***notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval, and***
- ***flow down to the supply chain the applicable requirements including customer requirements,***

h) records retention requirements, and

i) right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records

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.

NOTE 1 Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.

NOTE 2 Verification activities can include

- ***obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records),***
- ***inspection and audit at the supplier's premises,***
- ***review of the required documentation,***
- ***inspection of products upon receipt, and***
- ***delegation of verification to the supplier or supplier certification.***

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

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,

***NOTE** This information can include drawings, parts lists, materials and process specifications.*

b) the availability of work instructions, as necessary,

***NOTE** Work instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.*

c) the use of suitable equipment,

***NOTE** Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.*

d) the availability and use of monitoring and measuring equipment,

e) the implementation of monitoring and measurement,

f) the implementation of product release, delivery and post-delivery activities,

g) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),

h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,

i) provision for the prevention, detection and removal of foreign objects,

j) monitoring and control of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and

k) criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Planning shall consider, as appropriate

- ***establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,***
- ***designing, manufacturing and using tooling to measure variable data,***
- ***identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and***
- ***special processes (see 7.5.2).***

7.5.1.1 Production Process Verification

The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

NOTE ***This activity is often referred to as first article inspection.***

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes shall be identified.

The organization shall control and document changes affecting processes, production equipment, tools or software programs.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.

7.5.1.4 Post-Delivery Support

Post-delivery support shall provide as applicable for the

a) collection and analysis of in-service data,

b) actions to be taken, including investigation and reporting, when problems are detected after delivery,

c) control and updating of technical documentation,

d) approval, control and use of repair schemes, and

e) controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

7.5.2 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.

NOTE ***These processes are often referred to as special processes.***

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 maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

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

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE ***Traceability requirements can include***

- ***identification to be maintained throughout the product life,***
- ***the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap),***
- ***for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and***
- ***for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.***

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained ***(see 7.1.3)***.

7.5.4 Customer Property

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 4.2.4).

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.

Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

a) cleaning,

b) prevention, detection and removal of foreign objects,

c) special handling for sensitive products,

d) marking and labeling including safety warnings,

e) shelf life control and stock rotation, and

f) special handling for hazardous materials..

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 maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

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 ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

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.

The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

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.

NOTE According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support

- ***design verification (e.g., reliability, maintainability, safety),***
- ***process control,***
  - ***selection and inspection of key characteristics,***
  - ***process capability measurements,***
  - ***statistical process control,***
  - ***design of experiment,***
- ***inspection, and***
- ***failure mode, effect and criticality analysis.***

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.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Organizations shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

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 arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

NOTE ***Planned arrangements include customer contractual requirements.***

b) is effectively implemented and maintained.

An audit programme 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.

In the event of process nonconformity, the organization shall

a) take appropriate action to correct the nonconforming process,

b) evaluate whether the process nonconformity has resulted in product nonconformity,

c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and

d) identify and control any nonconforming product (see 8.3).

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.

Measurement requirements for product acceptance shall be documented and shall include

a) criteria for acceptance and/or rejection,

b) where in the sequence measurement and testing operations are to be performed,

c) required records of the measurement results (at a minimum, indication of acceptance or rejection), and

d) any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.

When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The organization shall ensure that all documents required to accompany the product are present at delivery.

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.

NOTE The term "nonconforming product" includes nonconforming product returned by a customer.

The organization's documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable, the organization shall deal with nonconforming 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***;***

— ***The organization's nonconforming product control process shall provide for timely reporting of delivered nonconforming product;***

NOTE Parties requiring notification of nonconforming product can include suppliers, internal organizations, ***customers, distributors and regulatory authorities.***

e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.

NOTE Authorized representative includes personnel having delegated authority from the design organization.

The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

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 analyse 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 requirements (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).

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.

The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

***NOTE** Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.*

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),

f) reviewing the effectiveness of the corrective action taken***,***

g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,

h) specific actions where timely and/or effective corrective actions are not achieved, and

i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

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

***NOTE** Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.*

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