

ISO 9001 Quality Assurance

1 Management Responsibility

1.1 General

The organization's management with executive responsibility shall define, document and demonstrate its responsibilities, continuous involvement and commitment for fulfillment of customer needs and requirements by

- a) establishing the organization's quality policy and quality objectives;
- b) establishing a quality management system as required in this International Standard;
- c) ensuring the availability of necessary resources and that all personnel concerned are fully aware of customer needs and requirements;
- d) performing management reviews.

1.2 Stakeholder needs and requirements

For quality assurance purposes the principal stakeholder is the customer.

The organization shall establish and follow procedures to identify and define customer needs and requirements with the aim to achieve customer confidence in the provided products and services.

1.3 Quality Policy

The organization's management with executive responsibility shall define its policy for quality and ensure that it

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1 Management Responsibility

1.1 General

The commitment and involvement of the organization's management with executive responsibility is crucial for developing and implementing an effective and efficient quality management system.

The management with executive responsibility should focus the organization on sustained customer satisfaction while giving benefits to the other stakeholders.

The management with executive responsibility should

- set directions and communicate how to achieve customer satisfaction;
- define quality objectives and related targets;
- provide resources;
- encourage employee efforts and recognize the relevant positive outcomes;
- carry out periodic reviews of the quality results;
- develop a culture of continual improvement.
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1.2 Stakeholder needs and requirements

Every organization has several stakeholders each with typical expectations and needs. Each stakeholder expects his own benefits from positive quality trends within the organization. The organization's management should undertake necessary activities to give confidence to each stakeholder.

The needs of the stakeholders should be communicated throughout the organization.

1.3 Quality Policy

The organization's policy for quality should be consistent with other policies within the organization, be focused on customer satisfaction

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- a) includes commitment to quality for all levels of the organization;
- b) is relevant to its goals and the needs and requirements of its customers;
- c) provides a framework for setting and reviewing quality objectives;
- d) is documented, communicated, understood, implemented and maintained throughout the organization.

The quality policy shall be regularly reviewed for suitability and effectiveness.

1.4 Quality objectives and planning**1.4.1 Quality objectives**

The organization's management at relevant levels shall establish and maintain documented quality objectives consistent with the organization's quality policy.

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and take into account the needs and expectations of all stakeholders.

During development and maintenance of the quality policy the following issues should be considered

- results from management reviews;
- goals to be achieved;
- evaluation of risks and opportunities;
- analysis of competition and of market;
- capabilities (eg human, research and development, technology) to address key new requirements;
- capability of its suppliers and partners.
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1.4 Quality objectives and planning**1.4.1 Quality objectives**

The organization's management with executive responsibility should require that the organization's managers define and document quality objectives for the products, processes and activities under their responsibility. The quality objectives should be measurable and consistent with other objectives within the organization.

Quality objectives should at least address

- customer satisfaction consistent with applicable standards and proper business ethics;
- continuous improvement of processes;
- prevention of adverse effects resulting from the organization and its products on the society and the environment.

The quality objectives should be communicated to personnel responsible for the appropriate processes and activities.

All employees, including newly hired, part-time and temporary employees, should understand the quality objectives and the commitment needed to achieve these objectives.

ISO 9001 Quality Assurance**1.4.2 Quality planning**

The organization's management shall define and document how the quality requirements for products and related processes will be met. Quality planning shall be consistent with all other requirements of the organization's quality management system and shall be documented in a format to suit the organization's operating practice.

The organization shall give consideration to the following issues, as appropriate, in meeting the specified quality requirements:

- a) quality objectives and quality plans;
- b) allocation of specific resources, responsibilities and authority needed;
- c) processes that constitute the organization's operating practice and which specific documented procedures and instructions to apply;
- d) identification and acquisition of any equipment, resources and skills that may be needed;
- e) identification of suitable verification at appropriate stages during the realization and delivery of the product;
- f) clarification of standards of acceptability for all quality requirements, including those which contain subjective judgment;
- g) need for and preparation of quality records.

1.5 Quality management system**1.5.1 General**

The organization's management shall establish, document and maintain a quality management system as a means of ensuring that products conform to specified requirements.

The quality management system shall be structured and adapted to the organization's particular type of business taking into account the appropriate elements in this International

ISO 9004 Quality Management**1.4.2 Quality planning**

The organizations management should define and document how the quality objectives will be met. Included in the planning should be a responsibility for ensuring that quality requirements include, as appropriate, provisions for safety, potential liabilities and means to minimize risks to personnel, customers and the environment.

The quality plans may include references to the appropriate documented procedures that form an integral part of the organization's quality management system. They may also constitute parts of a larger overall plan.

Quality planning should enable the organization to improve its quality performance. The resulting plans should be revised regularly to reflect changes in organizational objectives.

1.5 Quality management system**1.5.1 General**

A quality management system is the integration of organizational structure, procedures, processes and resources needed to achieve the established quality objectives and produce benefits for all stakeholders, customers, owners, employees, society and suppliers.

The quality management system should function in a manner which focuses on

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Standard.

1.5.2 Organizational structure

The responsibility, authority and the interrelation of personnel, including interfaces, shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of non-conformities relating to the product, process and quality management system;
- b) identify and record problems relating to the product, process and quality management system;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery or installation of non-conforming product until the deficiency or unsatisfactory condition has been corrected.

1.5.3 Quality Manual

The organization shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality management system procedures and outline the structure of the

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- continual improvement and sustained customer satisfaction;
- review of processes to assure that they are effective and efficient;
- that the system is implemented and maintained and is effective and efficient;
- that the products actually do satisfy customer needs and expectations;
- that the needs of both society and the environment have been addressed;
- problem prevention rather than dependence on detection after occurrence;
- the development and implementation of an appropriate quality improvement system

1.5.2 Organizational structure

In organizing a well structured and effective quality management system, emphasis should be placed on the identification of potential or actual quality problems and the implementation of preventive or corrective action.

General and specific quality-related responsibilities should be explicitly defined. Responsibility and authority related to each activity contributing to quality should be clearly established.

1.5.3 Quality Manual

The primary purpose of a quality manual is to outline the structure of a quality management system serving as a reference in the implementation and maintenance of the system. The organization is free to structure the quality

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documentation used in the quality management system.

1.5.4 System procedures

The organizations management shall

- a) prepare documented system procedures consistent with the requirements of this International Standard and the organization's quality policy, and
- b) effectively implement the quality management system and its documented procedures.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality management system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the work. Document control for system documentation shall be handled per clause 3.1.4.

1.5.5 Management representative

The organization's management with executive responsibility shall appoint a member of the organization's own management who, irrespective of other responsibilities, shall have defined authority for

- a) ensuring that a quality management system is established, implemented and maintained in accordance with the requirements in this International Standard, and
- b) reporting on the performance of the quality management system to the organization's management for review.

1.6 Management Review

The organization's quality system shall be reviewed by the management with executive

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management system documentation in a way that is suitable for its business.

Documented procedures should be established for making changes, modifications, revisions or additions to the contents of a quality manual

1.5.4 System procedures

All documented system procedures should be stated simply, unambiguously and understandably, and should specify the objectives and performance of the various processes or activities which have an impact on the effectiveness and efficiency of the quality management system.

1.5.5 Management representative

The management representative should report directly to the organization's chief executive officer and should regularly participate in management meetings where quality matters are discussed.

1.6 Management Review

The management reviews should consist of well-structured and comprehensive evaluations such as

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responsibility and in addition by persons from other appropriate management levels, at defined intervals sufficient to ensure its continuing suitability, adequacy and effectiveness in satisfying the requirements of this International Standard and the organization's quality policy and objectives.

Records of such management reviews shall be documented.

2 RESOURCE MANAGEMENT**2.1 General**

Management shall provide resources needed for the implementation and control of the quality system. Resources include human resources and other resources such as information, infrastructure, work environment and financial resources.

2.2 Human Resources**2.2.1 Deployment of Personnel**

The responsibilities, authorities and functions of personnel as defined by management, shall be communicated to enable effective deployment.

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- results from audits centered on various elements of the quality system;
- analysis of customer satisfaction, including customer feedback information;
- analysis of competition and of market;
- relevance of existing quality policy and quality objectives;
- the overall effectiveness in satisfying the guidance in this International Standard;
- considerations for updating the quality system, including the quality policy and quality objectives, in relation to changes brought about by new technologies, quality concepts, market strategies, and social or environmental conditions;
- the need or opportunity for improvement.

Observations, conclusions and recommendations issued as a result of such review should be documented for necessary action.

2 RESOURCE MANAGEMENT**2.1 General**

Appropriate human and other resources (e.g. information, infrastructure, work environment and financial resources) essential to the implementation of an organisation's policies and the achievement of its objectives should be defined and made available. In allocating resources, organisations can develop procedures to track the benefits as well as the costs of their activities.

2.2 Human Resources**2.2.1 Deployment of Personnel**

Functions, responsibilities and authorities related to the quality system should be clearly established within the overall organisational structure. The efficiency of the organisation depends on the

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2.2.2 Training and Qualification

The organisation shall identify training needs. It shall require that all personnel whose function impacts upon the quality of the intended product and service, is qualified.

Documented procedures for the control of education, training and qualification of personnel shall be applied in order to provide for systematic development of organisational competence.

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effective communication of the above.

2.2.2 Training, Qualification and Awareness

The qualification and competence necessary to achieve the organisation's objectives should be identified. This should be considered in personnel selection, recruitment, training, development of skills and ongoing education.

Appropriate training relevant to the achievement of policies and objectives should be provided to all personnel within an organisation. Employees should have an appropriate knowledge base, which includes training in the methods and skills required to perform their tasks in an efficient and competent fashion and knowledge of the impact their activities can have on the efficiency if performed incorrectly.

The organisation should also ensure that contractors working at the site provide evidence that they have the requisite knowledge and skills to perform the work in a responsible manner.

Education and training is needed to ensure that employees have appropriate and current knowledge of regulatory requirements, internal standards, the organisation's policies and objectives and work procedures. The level and detail of training may vary according to the task.

Training programmes typically have the following elements:

- identification of employee training needs;
- development of a training plan to address defined needs;
- verification of conformance of training programme to regulatory or organisational requirements;
- training of target employee groups;

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- documentation of training received;
- evaluation of training received.

Top management has a key role to play in building awareness and motivating employees by explaining the organisation's values and communicating its commitment to the policies. It is the commitment of the individual people, in the context of shared values, that transforms a quality system from paperwork into an effective process.

All members of the organisation should understand and be encouraged to accept the importance of achieving the objectives for which they are responsible and/or accountable. They in turn should encourage, where necessary, the other members of their organisation to respond in a similar manner.

Motivation to continually improve can be enhanced when employees are recognised for achieving objectives and targets and encouraged to make suggestions that can lead to improved performance. (See also 2.3.3 Work environment)

2.3 OTHER RESOURCES

2.3.1 Information

Information, including data and knowledge, necessary for the quality of the intended product and service shall be defined.

Systems for control, access and protection of such information shall be documented, implemented and maintained.

2.3 OTHER RESOURCES

2.3.1 Information

To provide for systematic control, internal and external information including data and knowledge should be identified relating to activities such as:

- Contracting
- Designing
- Process Control
- Verification and Testing
- Compliance with Legislation
- Protection of Intellectual Property
- Managing Personnel

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Note: For aspects of data control see section 3.1.4

The method for information acquisition should be appropriate and facilitate accuracy and legibility. Methods could include any or all of the following:

- Documentation
- Electronic media
- Magnetic media
- Visual media

In all cases, the method should be defined in associated control plans and work instructions. Suitable training should be provided which includes understanding of the use and importance of the information.

2.3.2 Infrastructure

The organisation shall define, document, implement, maintain, and evaluate its infrastructure necessary for product and service realisation.

2.3.2 Infrastructure

Each organisation needs an infrastructure to provide the underlying foundation for its operations. The infrastructure may include plants, workspace, hardware, software, tools, services, standards, and facilities, depending on the organisation's intended products and services. The reliability, availability, and maintainability of the infrastructure are vital to an organisation's quality management program.

The organisation should define its infrastructure requirements. These requirements should include:

The organisation's infrastructure needs, specified in terms such as functionality, performance, safety, security, availability, space, equipment, cost, time constraint.

- The infrastructure items selected to satisfy the organisation's needs, the functions that they perform, and the services that they provide.

The organisation should establish and install its

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infrastructure according to the infrastructure requirements.

The organisation should document its infrastructure configuration. The configuration documentation should include, as appropriate, buildings, rooms, offices, laboratories, work areas, transport systems, equipment, storage, telecommunication systems, communication services, etc. In addition, the extent to which infrastructure elements should be kept under configuration management should also be identified and documented.

The organisation should define and document an infrastructure maintenance program ensuring that the infrastructure continues to meet the infrastructure requirements. The infrastructure maintenance document should specify the type and frequency of needed maintenance and verification of proper operation of each infrastructure element, based on its criticality and usage. The organisation should maintain its infrastructure according to the infrastructure maintenance program.

The organisation should define and document an infrastructure evaluation program. The evaluation program should include:

- An evaluation of the infrastructure requirements, ensuring that they address all the organisation's infrastructure needs.
- An evaluation of the infrastructure configuration, ensuring it meets all the infrastructure requirements.
- An evaluation of the infrastructure maintenance, ensuring that the infrastructure is maintained as needed.
- How often and when an evaluation should be done.

2.3.3 Work Environment

The organisation shall define, document, implement, maintain and evaluate the human and physical aspects of the work environment needed

2.3.3 Work Environment

The work environment in the organisation is a compound of human aspects and physical aspects.

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to ensure the quality of the intended product or service.

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These aspects can have influence on the characteristics of the product as well as on the efficiency of the organisation.

The human aspects are especially important in a service organisation, whilst physical aspects are more important in a process industry.

Human aspects:

As a spur to the motivation, development, communication and performance of personnel, the organisation should consider aspects such as:

- creative work methods and opportunities for greater involvement to realise the potential of every member of the organisation;
- understanding of the objectives to be achieved and how they affect quality;
- due recognition and reward for achievement and improvement;
- career planning and development;
- safety rules and procedures.

Physical aspects:

Where they are important for the uniformity of the processes and the efficiency, the organisation should consider aspects such as:

- auxiliary materials and utilities (water, compressed air, electric power, fuels, chemicals) used for processing;
- temperature, humidity, cleanliness.

Based on the considerations above, the organisation should identify, specify limits, define verification and evaluate procedures for those aspects which have negative effect on the product quality, safety and efficiency of the organisation. Changes should result in revision of the pertinent procedures.

Note nn: Consideration should be given to the identification of any aspect relevant to control

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negative effects over the environment, both inside and outside the organisation's premises. These aspects are covered by the environmental management standards. See ISO 14000 family.

2.3.4 Finance

It is the purpose of the financial resource management to plan and control financial resources.

Financial resource planning should include activities for identifying needs for and sources of financial resources, estimating, scheduling, and allocating financial resources. The control of financial resources should include activities for comparing actual usage against finance plans and taking necessary action.

The financial reporting of quality related activities and the quality system should be reviewed in a timely manner for improvement. The financial reporting of quality related activities should be prepared and regularly provided to and monitored by management, and be related to other business measures such as "sales", "turnover" or "added value" in order to provide for a realistic, entrepreneurial:

- evaluation of the adequacy and effectiveness of the quality system,
- identification of additional areas requiring attention and improvement, and
- establishment of quality and cost objectives for the following period.

It is important that the effectiveness and efficiency of a quality system be measured in financial terms. The impact of an effective and efficient quality system upon the organisation's profit and loss statement can be highly significant, particularly by

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improvement of operations, resulting in reduced losses due to error and by making a contribution to customer satisfaction. Such measurement and reporting can provide a means for identifying ineffective or inefficient activities, and initiating internal improvement activities.

By reporting quality system activities and effectiveness and efficiency in financial terms, management will receive the results in a common business language from all departments.

The financial approach to the process for evaluation and reporting of the quality system should be planned and implemented. The approach to financial reporting selected and used by particular organisations will be dependent upon their individual structures, their activities, and the maturity of their quality systems. There are various approaches to gathering, presenting and analysing the elements of financial data. The approaches such as "quality cost," "process-cost" and "quality loss" have been found to be useful, but do not exclude others, or adaptations or combinations of them. These approaches are widely described in literature.

The elements of financial quality reports are in many cases already available in the organisation, but in other forms. The reporting as a financial quality report to give inputs to each approach adopted can require regrouping of individual elements from other reports.

3 PROCESS MANAGEMENT

3.1- Management Of Processes

3.1.1 General

3 PROCESS MANAGEMENT

3.1- Management Of Processes

3.1.1 General

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The organisation shall identify and manage processes necessary to provide assurance that products and services will meet customer requirements.

.This section identifies requirements relating to the management of processes normally considered necessary to assure product or service quality. The organisation may exclude from its quality management system certain of these requirements where it can be shown they are not applicable and will not affect its ability to meet customer requirements.

Such exclusions shall

- be supported by a documented rationale that the excluded requirement will not result in a risk to quality
- be consistent with the requirements of other standards, regulations etc. applicable to the supply of their product or service
- be subject to periodic review to verify their continued validity.

The following text relates to responses to TG1.8.1 verification comments. It has been included for background information only. IT IS NOT INTENDED THAT THIS TEXT WILL BE INCLUDED IN SUBSEQUENT DRAFTS.

The use of "products and services" was challenged by TG 1.8.1. It has been retained on the basis that

- **using "product" in accordance with the ISO definition creates an insurmountable barrier to creating a document which will be perceived as being equally relevant to all sectors.**
- **It enhances compatibility with ISO 14001**

With respect to the paragraphs above which

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The organisation should identify and manage those processes that are associated with the effective and efficient achievement of its policy, objectives and targets. In identifying such processes the needs of all the organisations stakeholders should be considered.

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deal with auditable requirements relating to "tailoring" it is recommended that

- the introduction of the standard deals with the general concept of tailoring and "how" it should be used
- only Section 3 should be capable of being tailored since this should accommodate all the differences between the current ISO9001 and 9002 and the significant majority of the differences between the current ISO9001 and 9003 particularly those which can continue to be readily justified

The use of "risk" was challenged by TG1.8.1. It has been retained on the basis that the alternative "does not affect product quality" does not provide sufficient guarantee that tailoring will not become a licence to ignore parts of the standard. The use of "risk" is also consistent with the output of TG1.3.3

3.1.2 Structure & Interaction of Processes

To ensure that interrelated processes work together effectively the organisation shall

- review the activities undertaken and identify those processes which affect the quality of supplied products and services
- plan the sequence and interaction of these processes
- identify and implement requirements for linkage and feedback between processes
- monitor key inputs, activities and outputs to verify that individual processes link together effectively
- use the results of monitoring to identify opportunities for improvement to the structure and interaction of quality related processes.

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To ensure all processes operate as an efficient network the organisation should undertake an analysis of how all processes, inputs and outputs interrelate.

In conducting the analysis and determining subsequent actions particular consideration should be given to

- processes which produce outputs directly related to customer requirements
- processes which produce outputs affecting needs of other stakeholders, for example, shareholders, employees, suppliers and society
- processes which produce outputs affecting the efficiency of other processes

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3.1.3 Responsibility and Authority

To ensure clarity of allocation of responsibilities and authority the organisation shall define and document

- key responsibilities for development , operation and control of quality related processes
- limits of authority
- reporting structures and interrelations

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Effectiveness and efficiency of process interaction should be achieved by establishing

- criteria for measuring process performance and robustness
- methods for verifying that interfaces between processes operate effectively
- methods to identify opportunities for time and cost reduction within the network of organisational processes
- feedback loops that facilitate continual improvement across all processes

3.1.3 Responsibility and Authority

In order that all processes in the organisation can operate effectively, responsibilities and authorities for action should be clear and be able to be understood by appropriate personnel

The way in which responsibilities and authority for processes are assigned should be compatible with

- the organizational objectives and culture,
- size of organisation, and product sector
- stakeholders needs,

It should reflect the need to ensure

- there is clear ownership and accountability for process performance
- people have the freedom to act within their areas of responsibility and authority
- there is compatibility of accountability and resource allocation
- that lines of reporting do not impede effective and efficient communication.

The assignment of process ownership and accountability should be subject to periodic review to ensure that it remains appropriate to the organizations policy and objectives.

ISO 9001 Quality Assurance**3.1.4 Documentation and data control****(a) Documentation required**

To enable quality related processes to be systematically and consistently managed the organisation shall establish appropriate documentation relating to these processes.

This documentation shall

- include documented procedures where their absence could adversely affect quality
- stipulate information and /or operating criteria to support the effective operation of the processes.

The range and detail of such documentation shall be dependant upon the complexity of the process, the methods used and the skills and training needed by personnel involved in carrying out the activity

(b) Documentation and data control

The organisation shall establish and maintain procedures for controlling all documents and data required for the management of processes, to ensure that

- they can be located;
- they are periodically reviewed, revised as necessary and approved for adequacy by authorised personnel;
- the current versions of relevant documents are available at all locations where operations essential to the effective functioning of the process are performed;
- obsolete documents are promptly removed from all points of issue and points of use, or otherwise assured against unintended use;
- any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified

ISO 9004 Quality Management**3.1.4 Documentation and data control**

The output from the analysis outlined in 3.1.2 above should be used to establish documentation (e.g. procedures) defining inputs, key controls and outputs for each identified process.

Such documentation should establish a basis for

- setting and communicating key features of the processes
- training in process responsibilities and activities
- sharing knowledge and experience in teams and work groups
- measurement and audit of process performance
- review and improvement of processes

The organisation should review the range and detail of the procedures and the data collected to confirm the continuing effectiveness and efficiency of the documented system.

Consideration should be given to

- whether additional procedures or data are required for improved process efficiency
- whether the existing documentation has supported process efficiency rather than impose unnecessary bureaucracy

The organisation should ensure that the process procedures and the methods of collecting and retaining data are user friendly and efficient

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Documentation shall be legible, revision controlled and readily identifiable, maintained in an orderly manner and retained for a specified period. Procedures and responsibilities shall be established and maintained concerning the creation and modification of the various types of document.

c) Document and data changes

Changes to documents and data required for process management shall be reviewed and approved by the same functions/organisations that performed the original review and approval, unless specifically designated otherwise. The designated functions/ organisations shall have access to pertinent background information upon which to base their review and approval.

Where practical the nature of the change shall be identified in the document or the appropriate attachments.

3.2 Customer (ISO 9001)**3.2.1 Identification of customer needs & expectations**

The organization shall establish, to the extent necessary to ensure customer satisfaction, a process for identifying the requirements of their customers and /or market.

This process shall give consideration to the following

- the extent to which customer needs are formally specified
- the necessity for the organisation to define product or service requirements based on

3.2 Customer (ISO 9004)**3.2.1 Identification of customer needs & expectations**

In order to focus on achieving benefits for all stakeholders the organisation should clearly identify who it wishes to categorise as "customers". In addition to those with whom there is a contractual relationship to provide a product or service, consideration should be given to

- users of the service or product who are not direct customers
- internal customers of the various processes within the organisation

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- customer needs
- implied or unstated needs which must be addressed to ensure fitness for purpose of the product or service
 - obligations in relation to the product or service including warranties, liabilities and legal compliance
 - customer expectations for the availability and delivery of the product or service
 - the need to maintain confidentiality or to protect customer data and information
 - the need to create records to facilitate any review of customer requirements

3.2.2 Review of customer needs and expectations

The output of the process for identifying customer requirements shall be reviewed before a commitment to supply a product or deliver a service is made to the customer. (e.g. submission of a tender or acceptance of a contract or order

This review shall ensure

- the requirements are adequately defined and documented

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- associated organisations
- shareholders
- regulators
- others who perceive they have a stake in the performance of the product

The organization should have an understanding of all "customer" needs and expectations.

Consideration should be given to the use of

- market research
- competitor analyses,
- product and service benchmarking,
- customer satisfaction surveys
- customer and user needs surveys,
- customer feedback.
- studies of internal customer needs
- studies of needs of associated companies,
- monitoring of regulatory developments

The organisation should consider how the "customer" needs and expectations identified would be best analysed and the results communicated within the organisation. Where appropriate, identified needs and expectations should be documented in preliminary specifications as the basis for subsequent development work.

3.2.2 Review of customer needs and expectations

To promote effective decisions and actions the organisation should undertake an analysis and review of available data and information..

The review should deal with the needs and expectations identified to determine

- anticipated changes to customer and market requirements

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- where no written statement of requirement is available for an order received by verbal means a record of the order requirements has been established
- any contract or accepted order requirements differing from those in their tender are resolved.
- records of the outcome of the review are retained

The above review provisions shall also be applied to customer order amendments.

3.2.3 Review of organizational capability to meet defined needs

Each commitment to supply a product or service (including accepted tenders, contracts and orders) shall be reviewed to ensure that the organization has the capability to meet the defined requirements. Records of such reviews shall be retained.

Before a commitment is made for the supply of a new product or service the organisation shall ensure that the need for any additional resources and processes is considered.

The organization shall identify how any amendment to order is reviewed against organisational capability and the changed requirements communicated to concerned functions within the organization.

3.2.4 Customer communication

The organization shall: implement effective liaison with customers to the extent necessary to support the meeting of customer requirements. In establishing its arrangements for liaison the organisation shall give consideration to the

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- the adequacy of existing product and service specifications
- potential risks to organisational performance
- market perceptions of product and service performance

The output of this review should provide a basis for establishing

- development needs and opportunities
- internal objectives and targets for efficient organisational performance
- inputs into business planning

3.2.3 Review of organizational capability to meet defined needs

The organisation should confirm its capability to respond to the needs and expectations of all its stakeholders.

A process should be established which

- utilises the output of 3.2.1 and 3.2.2 above,
- confirms their compatibility with the organisations agreed objectives and
- establishes action plans to remedy any deficiencies in organisational capability.

In many instances this will be conducted in relation to a review of the continued adequacy of the organisations objectives and plans.

3.2.4 Customer communication

Effective customer communications are an essential prerequisite for maintaining organisational objectives and actions in alignment with customer needs and user expectations. The organisation should consider establishing

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communication requirements relating to

- product or service information
- enquiry and order handling
- receipt and processing of customer order amendments
- customer feedback on supply and delivery
- customer complaints and other reports relating to potential product nonconformities;
- product recall processes, where appropriate
- customer feedback on performance

3.3 Process Operations**3.3.1 General**

The organisation shall define, plan and document those processes which directly affect quality.

To provide a basis for confidence in consistent and effective operation the organisation shall

- define the significant process parameters that impact on product or service characteristics
- define the methods used to control critical process
- ensure the availability of appropriate process documentation (Ref 3.1.4.(a)) for use by relevant personnel
- document or reference applicable development plans, quality plans or other planning documentation
- where appropriate, define standards and codes of practice relevant to particular processes.

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channels for communication with all stakeholders to enable timely transfer of information and well informed responses by all parties. In determining communication needs particular attention should be given to the content of 3.2.1.

The organisation should ensure that information provided to customers and users of their products and services enhances their reputation and future customer loyalty.

The information should

- facilitate customers to achieve the intended benefits for the whole of the intended period of use or application of the product or service
- assist users and other affected parties to avoid potential risks associated with the product or service

encourage feedback on product or service performance, user expectations and suggested enhancements

3.3 Process Operations**3.3.1 General**

Quality should be built in to all organizational processes. Inadequate planning and control of any process will lead to deterioration performance and a potential loss of efficiency. This requires all aspects that affect both the robustness of processes and the demands that are to be made of the process to be considered as part of planning of process operations.

Processes should be designed so that

- inputs, key activities and outputs are clearly defined and controlled
- they can interact effectively where linkage is required
- they achieve the desired capability of the process and results

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- define the arrangements for measurement, monitoring, verification, recording and controlling to ensure that processes are operating effectively and the resultant product meets specified requirements.

The organisation shall give consideration to

- the capability of processes to be operated and maintained
- personnel training and qualification requirements for process activities
- the facilities, equipment, materials and software necessary to support a process

3.3.2 Design and development**(a) General**

The requirements of this section are

- relevant to the design and development of all product and service categories (i.e. hardware, software, processed materials and services)
- applicable to the design and development of any critical process operations where their effectiveness cannot be guaranteed by any other means (See 3.3.4(b) below.)

The requirements need not be applied to service or product customisation where the operation of the quality planning process (1.4.2) and the customer processes (3.2.1 to 3.2.2) ensures that the required product or service is adequately specified.

In establishing the range and scope of application of design and development requirements the organisation shall ensure compliance with Section 3.1.1.

The documentation required by Section 3.1.4 shall be sufficient to ensure that the design and development activity

- meets the requirements identified as essential

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- they incorporate provision for feedback as a basis for continual improvement of both product and process.

3.3.2 Design and development

To promote the efficiency of its operations the organisation should apply the principles of ISO9001 Section 3.3.2 to the development of all its key processes whether they be product related processes or business processes.

When designing processes the following should be considered

- how processes may be able to be simplified so as to reduce time cost and risk
- the need for controls to be developed which enable process errors to be corrected before they result in a loss of quality or value whether that loss is internal or external
- how the design of the product or service affects the efficiency of the processes required to produce that product or service.

Systems should be developed for a feedback from production and service provision processes to provide design inputs to the product design .

These inputs should be used to ensure there is the greatest compatibility practical between the product design features to ensure customer satisfaction and the ease by which that product can be produced or delivered. Consideration

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for customer satisfaction

- results in a product that is fit for its intended application

(b) Design and development planning

The organisation shall prepare plans for each design and development project. These plans shall describe or reference

- the project objectives and expected outputs
- the various stages of the design and development process
- design and development methodologies
- the arrangements to ensure the disciplined and orderly conduct of the design and development project
- key review, verification and validation activities

The plans and associated documentation shall be

- distributed to relevant personnel
- regularly reviewed and updated as design and development evolves.

The design and development activities shall be assigned to qualified personnel equipped with adequate resources and appropriate information.

The arrangements for communication between different groups (or individuals) involved in a design and development project, both internal and external to the organisation, shall be defined.

The respective responsibilities and lines of reporting between such groups shall be clearly established. The authority over the various aspects of the design and development process shall be defined.

(c) Design and development inputs.

The requirements relating to the product or service and their intended application shall be

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should be given to at least the following

- relationships between user needs, product or service features and the capability for trouble free operation of the processes.
- the implications for resource and material requirements
- potential problems of maintainability of process equipment
- potential measurement problems

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identified and documented. Applicable statutory and regulatory requirements and any other inputs that will contribute towards the realisation of the design and development shall also be identified. The organisation shall undertake a review to confirm the completeness and adequacy of the design and development inputs. Records shall be maintained of incomplete, ambiguous or conflicting requirements and the outcome of subsequent actions taken to deal with them.

(d) Design and development outputs

The outputs of the design and development process shall be documented and expressed in a manner that allows them to be verified against relevant input requirements.

Design and development output shall:

- meet the design and development input requirements
- contain or make reference to acceptance criteria
- identify those characteristics of the design that are crucial to the safe and proper use and application of the product or service.

Design and development output documents shall be subject to appropriate review and approval before release for use.

(e) Design Review

At appropriate stages of design and development, a formal, systematic and critical review of the results so far shall be conducted by suitably qualified persons. The review process shall address, as a minimum

- the adequacy of design outputs
- points on which any decision is outstanding

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- problem areas and potential shortcomings
- any identified deficiencies in the set up of the project or the operation of the design and development process
- actions required as a result of the review.

Participants in the design review process shall include representatives of all functions concerned with the design stage being reviewed.

Records of the design reviews and subsequent follow up actions shall be maintained.

(f) Design and development verification.

At appropriate stages of design and development verification shall be performed to ensure that the design output meets the design input requirements. The design verification records shall be maintained.

Note in addition to conducting design reviews, design verification may include activities such as

- comparing the new design with a similar proven design, if available
- undertaking tests and demonstrations
- undertaking alternative methods of analysis
- reviewing the design stage documents before releases

(g) Product and service validation

Validation shall be performed to the maximum extent practical to ensure that the product or service conforms to defined user needs and/or requirements.

Validation is necessary to confirm that the proposed end product or service is capable of meeting the needs of customers under anticipated conditions. Wherever possible it shall be defined, planned and completed prior to the delivery of

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the product or implementation of the service. Partial validation of the design or development outputs may be necessary to provide confidence in their adequacy for use in production, construction or delivery. Such partial validation may use methods such as

- reviews involving other stakeholders
- modelling and simulation studies
- production, construction or delivery trials of key aspects of the product or service.

(h) Configuration management

The organisation shall initiate technical and administrative disciplines, during the design and development processes, to ensure control of the status and arrangement of the various elements that will make up or contribute to the product or service.

The disciplines adopted shall facilitate

- the unique identification of different versions of the designed or developed product or service
- the identification and control of the status of items during the design and development process
- the control of related documentation, hardware and software
- the use of correct and accurate information by everyone working on the product or service at any time during its life cycle
- the control of actions and changes resulting from modifications or change requests
- the effective communication of data and information relating to product or service configuration to all appropriate parties.
- provision of a basis for ensuring the continuing management of the configuration of

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the product or service, throughout its life cycle

The extent of controls adopted shall

- be compatible with the project size and complexity
- take into account the potential effect on quality arising from failures in configuration management
- ensure all design and development changes are identified, documented, reviewed and approved by appropriate personnel before their implementation.

3.3.3 Purchasing and procurement**(a) General**

The organisation shall establish controls over procurement and purchasing processes. These controls shall ensure acquired products or services which are intended for incorporation into their own products and services facilitate the achievement of customer satisfaction

(b) Supplier Selection

The organisation shall

- identify those purchased products or services which have a significant effect on the organisation's own ability to meet customer requirements
- evaluate and select suppliers on the basis of their ability to meet specified requirements including any relevant quality system or quality assurance requirements;
- establish and maintain quality records of acceptable subcontractors
- define the type and extent of control to be exercised over their various suppliers.

ISO 9004 Quality Management**3.3.3 Purchasing and procurement****(a) General**

Quality management systems aim to achieve quality by building it into the product at every stage and an extension of the purchasing and procurement system beyond the basic requirements can yield considerable benefits with respect to both effectiveness and efficiency. In this way, it is possible to place less reliance on inspection by the organization, while at the same time providing a high level of assurance on product quality. The control of purchased products plays a vital part in assuring final product quality. In the case of a service the purchased item may be presented to the customer without further processing, and may represent the most critical element of the service.

The quality system should specify an integrated set of controls which ensures that

- close and long-term working relationships are established with suppliers of critical products,
- the organisation can apply its verification resources selectively rather than achieve

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The controls applicable to the various suppliers and the products or services supplied shall be compatible with

- the type of product or service being supplied and the immediacy of its impact on the effectiveness of the organisations own processes
- the impact of product or service being supplied on the quality of final product
- ease of checking adequacy of the supplied product or service
- previously demonstrated capability and performance of these suppliers;
- the results of quality audit or other assessments of supplier capability, where available

(c) Purchasing data

Purchasing documents shall contain data clearly describing the product ordered, including, where applicable:

- the type, class, grade or other precise identification;
- the title or other positive identification, and applicable issue of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;
- the title, number and issue of any applicable quality system standard.

The organisation shall review and approve purchasing documents for adequacy of specified requirements prior to release.

(d) Verification of purchased product

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control of purchased products by inspection or testing.

It is in the interests of both supplier and purchaser that the ultimate goal of achieving customer satisfaction is attained. The organization can help improve the quality of purchases by assisting the supplier to develop his quality system. The old confrontational approach - let the buyer beware - should be avoided in favour of a mutual assistance approach.

A well-defined channel of communication between purchaser and supplier should be established that ensures

- quality matters can be handled and should operate at the level of normal contact between the two parties rather than at senior executive level only
- the overall purchasing procedure provides mechanisms for the resolution of quality problems or other disputes, including agreement on the return of non-conforming products
- provision is made for regular visits to the supplier's site, and reviews to be held between the two parties.

Frequent communication is recommended, especially in the case of critical purchases, even where there are no quality issues.

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Where the organisation, its customer or its customer's representative proposes to undertake verification activities at the supplier's premises, the organisation shall specify the required verification arrangements and the method of product release in the purchasing documents or associated documentation.

Note:

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer

3.3.4 Control of process operations

Production and service provision operations shall be subject to planned arrangements and controls. These shall ensure a consistent level of process capability which will result in the meeting of customer requirements.

In determining the arrangements and controls required the organisation shall give consideration to the following in addition to satisfying the requirements of 3.3.1

- i) the use of suitable production, installation, servicing and service provision equipment, and a suitable working environment.

Provision shall be made for the maintenance of such equipment and working environments to ensure continuing process capability. The type and extent of such maintenance shall be consistent with the potential risks of failing to meet defined product requirements;

- ii) the availability of criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations);
- iii) the availability and use of appropriate

ISO 9004 Quality Management**3.3.4 Control of process operations**

Planning for process control should include at least the following considerations:

- factors affecting the quality characteristics to be built into each step of the process should be identified, and control features for each of these should be established;
- factors affecting the efficiency of the process should be identified and corresponding control features established;
- measurement criteria and methodologies to support both of the above should be established

Consideration should be given to the preparation of a document which identifies all the measurable features relating to both quality characteristics and process efficiency as well as methods of process control for the whole process or its important parts. Such a document will contribute to examination of the effectiveness of process control planning and to process quality audit.

Processes should be verified as capable of

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inspection, measuring and test equipment that is capable of the necessary accuracy and precision

- iv) exercise of due care with respect to their customer's property while it is under the organisation's control or while it is being used by the organisation. Such control shall include the verification, storage and maintenance of customer supplied product provided for incorporation into the supplies or for related activities. Any customer product or property that is lost, damaged or is otherwise found to be unsuitable for use shall be recorded and reported to the customer;
- v) where appropriate, the identification of product by suitable means from receipt through all subsequent processes;
- vi) where and to the extent that traceability is a defined requirement, provision for the maintenance and recording of unique identification of individual product or batches;
- vii) provision of methods of handling product that prevent damage or deterioration;
- viii) the use of appropriate storage facilities to prevent damage or deterioration of product pending further processing, use or delivery;
- ix) application of appropriate methods of preservation and segregation of product while the product is under the organisation's control. Where product is liable to deterioration, the condition of product in stock shall be assessed at appropriate intervals;
- x) provision for identifying the status of product by suitable means which indicate the conformance or non-conformance of product with regard to inspection and tests performed;
- xi) provision for control of product movement and release to and from designated status categories and associated holding, storage and

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producing in accordance with product specifications utilizing statistical techniques wherever appropriate and practical. Before full scale processing commences, inherent variation of important quality characteristics or process control characteristics should be studied. When the variation is large compared to the specification width, i.e. process capability is unsatisfactory, one of the following measures should be taken:

- studying causes of variation and improving the process;
- reviewing specifications and modifying unnecessarily strict specifications, if appropriate;
- adopting enhanced levels of monitoring and inspection where this is the only basis for ensuring minimum standards are maintained

Where increased reliance on monitoring and inspection is found to be necessary consideration should be given to the application of the approaches outlined in 3.2.2 above to determine if a more efficient solution can be achieved through the design process.

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/or segregation areas and such that only product that has passed the required inspection and tests (or has been released under an authorised concession) is used, dispatched or installed.

- xii) control of packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements;
- xiii) protection of the quality of product after final inspection and test until such times that it is no longer the responsibility of the organisation

b) Process Validation

The organisation shall identify any processes

- the results of which cannot be fully verified by subsequent inspection and testing of the product or service or
- where processing deficiencies may become apparent only after the product is in use or the service has been delivered.

These processes shall be subject to some form of validation to demonstrate their effectiveness and acceptability.

The arrangements for validation shall be identified and recorded and shall give consideration to any need for

- such processes to be pre-qualified
- for the pre-qualification of equipment or personnel
- the use of specific procedural documentation or records

NOTE. Such processes requiring validation or pre-qualification of their process capability are frequently referred to as special processes..

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Records shall be maintained for qualified processes, equipment and personnel, as appropriate

3.3.5 Control of nonconforming product**a) General**

The organization shall ensure that any product or service which does not or will not conform to specified requirements is prevented from unintended use or installation.

The arrangements for ensuring the management of such situations until compliance with specified requirements can be re-established shall be specified in an appropriate documented procedure..

Control shall provide for identification, documentation and review of the problem encountered and its extent

b) Nonconformity review and disposition

Instances of nonconformity shall be reviewed with regard to the action to be taken. They may be:

- a) reworked or adjusted to meet the specified requirements, or
- b) accepted with or without correction by concession, or
- c) re - assigned for alternative applications, or
- d) rejected as unsuitable.

The responsibility for review and authority for the disposition of nonconformities shall be defined.

ISO 9004 Quality Management**3.3.5 Control of nonconforming product****a) General**

All personnel within the organization, particularly those engaged in process output verification of hardware, software, processed material or services should have the responsibility to report nonconformances at any stage of the process.

The mechanism for responding to nonconformances should include not only provision for long term action to avoid re-occurrence but also provision for review to monitor for re-occurrence. The person or persons responsible for this aspect of the management of non-compliances, corrective action, and monitoring should be defined. It is essential that all nonconformances are recorded, together with disposition, as the information will form part of the performance data base and provide information in the corrective action audit process.

b) Nonconforming product review and disposition

Nonconforming items should be subjected to review by designated persons to determine whether they constitute trends or whether they are a repetition of earlier occurrences which should have been prevented by the corrective action system. Persons carrying out the review should be competent to evaluate the effects of the nonconformity and have the authority and resource to deal with recurrent problems.

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When required by the contract, the proposed use or repair of nonconforming product or service (see 3.3.d.2.b) shall be reported for concession to the customer or customer's representative.

The description of any nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see control of quality records).

Repaired and reworked product shall be re-inspected in accordance with the quality plan and/or documented procedure requirements.

3.3.6 Delivery and post delivery services

When the functionality of products may depend on servicing for maintenance or proper use of the products and when the supplier provides for some or all product servicing by warrantee, by contract or as part of the initial delivery or installation process, the supplier's quality system shall include provisions for the types and extent of servicing provided. The following activities shall be considered as appropriate:

- clarification of servicing responsibilities among supplier, distributors and users;
- planning of service activities, whether carried out by the supplier or by a separate agent;
- validation of design and function of special-purpose tools or equipment for handling and servicing products after installation;
- control of measuring and test equipment used in field servicing and tests;
- provision and suitability of documentation, including instructions for use in dealing with the spares or parts lists, and in servicing of the product;
- provision for adequate back-up, to include technical advice and support, customer personnel training and spares or parts supply;
- training of servicing personnel;

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The effect of non-conformities on process efficiency should be monitored with particular emphasis on the effect of different methods of disposition.

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- provision of competent servicing personnel;
- feedback of information that would be useful for improving product or servicing design.
- other customer support activities.

4.0 Measurement, Analysis and Improvement**4.1 Measurement and Analysis****4.1.1 General**

The organisation shall establish and maintain a measurement and analysis process for verifying the results of product, process, system and customer satisfaction measures to provide for effective management and improvement of the quality system. These results, and a summary of the results of analysis of data (see 4.1.6) shall be an input to the management review process.

The type, location and frequency of measurements shall be dependent upon the importance of the characteristics, the level of delivered quality as perceived by the customer, the economics of quality, and the ease of verification during processing.

The organisation shall revise the measurements, their location or frequency as appropriate, based upon an analysis of the occurrence of nonconforming product and/or service as perceived by the customer, or as discovered through in-process, final inspection or product audit. Measurements, including revisions, shall be approved by authorised personnel, and recorded on the appropriate quality system documentation.

4.1.2 System Measures**4.1.2.1 Internal Audit**

The organisation shall carry out audits of its quality management system in order to determine if it

- 1) conforms to the plans requirements of the quality system; and
- 2) has been effectively implemented and maintained.

ISO 9004 Quality Management**4.0 Measurement, Analysis and Improvement****4.1 Measurement and Analysis****4.1.1 General**

The organization should provide for the collecting, analysing, summarizing and disseminating of pertinent information and data needed to monitor the organization's performance. This information and data should be used throughout the organization to support effective and efficient management of key organisational processes.

4.1.2 System Measures**4.1.2.1 Internal Audit**

The audit programme and procedures should provide an objective evaluation performed by qualified personnel of the organization's activities, planned and carried out to include the following:

- a) organisational structures;
- b) sales, administrative, operational and quality

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NOTE: Suitability and effectiveness of the quality management system is the responsibility of management, however effective implementation of the requirements of this international standard should be verified on a more frequent basis than "management review" by qualified personnel.

The organization's internal audit programme, including any schedule, shall be based on the status and importance of the activity to be audited, the results of previous audits and of other system measures.

The internal audit programme shall include as appropriate:

- a) planning and scheduling the specific activities and areas to be audited, also based upon other inputs which include organizational changes, market feedback, nonconforming reports, customer complaints, and surveys.
- b) assignment of personnel, independent of those having direct responsibility for the activity being audited, with appropriate qualifications to conduct audits
- c) a checklist used to provide a consistent base for the audit process
- d) follow up the results from previous audits
- e) audit reports containing the results of the audit.

The internal audit reports shall include:

- a) activities and areas audited
- b) nonconformities or deficiencies found
- c) corrective actions taken as a result of previous quality system audit nonconformities found
- d) opportunities for improvement

NOTE: Guidance on quality system audits is given in ISO 10011.

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system procedures;

- c) personnel, equipment and material resources;
- d) work areas, operations and processes;
- e) products being produced (to establish the degree of conformance to requirements);
- f) documentation, reports and record-keeping.

The efficiency of the internal audit process as defined in the audit programme and procedures should be evaluated, and results provided to the organisation's management for planning and implementing improvement activities.

ISO 9001 Quality Assurance**ISO 9004 Quality Management****4.1.3 Process Measures**

The process measurement process shall include:

1. criteria for selecting the quality characteristics of process performance requiring measurement,
2. the scope, type and frequency of measurement, and
3. methods for ensuring consistency, validity, standardisation, security, review, update and timely access of quality measurement data throughout the organisation, and to customers and suppliers as appropriate.

The organisation shall establish and maintain a programme and procedures for periodic process audits to be carried out to verify the effectiveness of implemented process controls to ensure that processes are performing consistently and in accordance with planned process design, and result in outputs that meet the specified requirements.

The organisation's process audit programme shall be based on the status and importance of the process to be audited, the results of previous audits and of other quality measures.

The process audit programme shall define the scope and frequency of the process audits.

The process audits shall be conducted by personnel independent of the processes being audited.

Where process deficiencies may become apparent only after the product is in use, and the results of processes cannot be directly verified by subsequent inspection or test of the product itself, such processes require qualification to ensure process capability and control of all critical variables during process operation.

The audit results shall be recorded and provided to the management of the audited area and summarised for the management review process.

NOTE: Process audits supplement the system and product measurement results, and can be integrated into the internal quality system audit where appropriate.

4.1.3 Process Measures

An organisation should not rely on verification activities to cause quality to happen. Process activity should be directed toward defect prevention methods, such as statistical process control, mistake proofing, visual controls, rather than defect detection.

The organisation shall evaluate the efficiency of key process controls to ensure that the controls are appropriate for the application they are being used for.

The measures used to control process performance should be audited at appropriate intervals to assure the continuing acceptability of

- a) the accuracy and variability of equipment used;
- b) the skill, capability and knowledge of operators;
- c) the accuracy of measurements results and data used to control the process;
- d) process environment and other factors affecting quality, such as time and temperature;
- e) appropriate documentation of process variables, equipment and personnel;
- f) process compliance with environmental policies, procedures, regulations and standards; and
- g) life-cycle-time performance.

Also, processes should be periodically verified as being capable of producing product and/or services in accordance with specifications and/or customer requirements.

ISO 9001 Quality Assurance**4.1.4 Product Measures**

The organisation shall establish and maintain documented procedures to monitor and measure its product and/or services in order to verify that the specified requirements for the product and/or service are met, with special attention on crucial characteristics, which are those where non-compliance could affect product safety, compliance with regulations, fit, function, appearance, or quality of subsequent manufacturing operations. The required inspection and testing activities to be established, and the records to be maintained, shall be detailed in the quality plan or quality system documentation.

The organisation shall determine the scope and frequency of the product measures used based upon the results of the system and process measures.

Acceptance criteria shall be defined by the organisation and approved by the customer when specified by contract.

NOTE: Acceptance criteria for any attribute data sampling plans used should be zero defects. The use of statistical sampling and evaluation procedures is important with processed materials (e.g. "bulk"). The use of control charts and statistical sampling procedures and plans are examples of techniques employed to facilitate production/process control.

ISO 9004 Quality Management**4.1.4 Product Measures**

With regard to product measures, the quality plan should indicate:

- a) any relevant inspection and test plan (the items below may all be part of an inspection and test plan)
- b) how the organisation will verify supplier product conformance to specified requirements
- c) where each inspection and test point is located in the process sequence
- d) what characteristics are to be inspected and tested at each point, the procedures and acceptance criteria to be used, and any special tools, techniques or personnel qualification required
- e) where the customer has established points for witness or verification of selected characteristics of a product or its production and installation processes
- f) where inspections or tests are required to be witnessed or performed by regulatory authorities
- g) where, when and how the organisation intends, or is required by the customer or regulatory authorities, to use qualified third parties to perform:
 - 1) type tests
 - 2) witness testing (including on-site acceptance)
 - 3) product verification
 - 4) product validation
 - 5) material, product, process, quality system or personnel certification

Prior to initial delivery of a service, the following should be reviewed to confirm:

1. the service is consistent with customer requirements
2. the service delivery process is complete

ISO 9001 Quality Assurance**ISO 9004 Quality Management****4.1.4.1 Receiving Inspection and Testing**

The organisation shall ensure that incoming product and/or service is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.

Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the supplier's premises and the recorded evidence of conformance provided.

4.1.4.2 In-process Inspection and Testing

The organisation shall inspect and test the product as required by the quality plan and/or documented procedures. The organisation shall hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures. Release under positive-recall procedures shall not preclude the activities outlined above.

NOTE: Verification should be made as close as possible to the point of realisation of the characteristic. If verification of characteristics of the process itself is not physically or economically practical or feasible, then verification of the product should be utilised. In all cases, relationships between in-process controls, their specifications and final product specifications should be developed, communicated to production

3. resources are available to meet the service obligations, particularly materials and personnel
4. that applicable codes of practice, standards, drawings and specifications are satisfied
5. information to customers in the use of the service is available.

4.1.4.1 Receiving Inspection and Testing

The organisation's incoming quality system should use one or more of the following methods:

1. Receipt and evaluation of statistical data
2. Receiving inspection and/or testing (e.g., sampling based on performance)
3. Second or third party assessments or audits of subcontractor sites, when coupled with records of acceptable quality performance
4. Part evaluation by accredited contractors or test laboratory

Procedures for control of purchased material should include quarantine areas or other appropriate methods to prevent unintended use or installation of non conforming materials.

4.1.4.2 In-process Inspection and Testing

Verification for hardware products may include the following:

- a) set-up and first-piece inspection
- b) inspections or tests by machine operator
- c) automatic inspection or test
- d) fixed inspection stations at intervals throughout the process
- e) monitoring specified operations by patrolling inspectors

Verifications at each stage should relate directly to finished product specifications or to an internal requirement, as appropriate.

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and inspection personnel, and documented.

4.1.4.3 Final Inspection and Testing

The organisation shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product and/or service shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorised.

NOTE: While remedial action is sometimes possible during service delivery, it is usually not possible to rely on final inspection to influence service quality at the customer interface where customer assessment of any nonconformity is often immediate.

4.1.4.4 Product Audit

The organization shall establish and maintain a programme and procedures for periodic product and/or service audits conducted after final inspection to verify the effectiveness of the verification activities implemented to ensure that products meet specified requirements, including product and/or service, packaging and labelling.

The organization's product audit programme shall be based on specified requirements, customer complaints, and the results of previous audits or other measures (see Section 4).

The product audit programme shall define the scope and frequency of the product audits.

NOTE: Where the customer quality performance requirements are met, the frequency of product audits may be reduced. Where nonconforming product is found, the frequency should be increased, and additional verification activities should be implemented

ISO 9004 Quality Management**4.1.4.3 Final Inspection and Testing**

The supplier should document the customer requirements, if any, for layout inspection and functional testing. A layout inspection should identify the actual dimensions of the product characteristics for comparison to the requirements. This is one method for monitoring tool wear.

4.1.4.4 Product Audit

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in the process.

The product audits shall be conducted by personnel independent of the persons conducting the work.

The product audit results shall be recorded and provided to the management of the audited area and summarised for the management review process.

NOTE: Product audits supplement the system and process measurement results.

4.1.4.5 Inspection and Test Records**4.1.4.5 Inspection and Test Records**

The organisation shall maintain records which provide evidence that the product and/or service has been inspected and/or tested in compliance with the quality plan, or documented procedures. These records shall show clearly whether the product and/or service has passed or failed the inspection and/or tests according to defined acceptance criteria. Where the product and/or service fails to pass any inspection and/or test, the procedures for control of nonconforming product and/or service shall apply.

Records shall identify the inspection authority responsible for the release of product and/or service.

4.1.4.6 Control of Measuring, Inspection and Test Equipment**4.1.4.6 Control of Measuring, Inspection and Test Equipment**

The organisation shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the organisation to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Evidence should be available to document that appropriate statistical studies have been conducted to analyze the variation present in the results of each type of measuring and test equipment system prior to their use. This requirement should apply to all measurement systems referenced in the quality system documentation.

NOTE: Additional guidance on measurement uncertainty may be found in ISO 10012-1: 1992 (E). The choice of the specific method to be used should be based upon sound technical knowledge of the complete measurement system, the conditions

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under which it will operate and the uses for which the data are being produced.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. The organisation shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.1.6).

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

The organisation shall:

1. determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;
2. identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;
3. define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria;
4. develop a reaction plan to be initiated when calibration verification results are unsatisfactory;
5. verify the validity of previous inspection and test results when equipment is found to be out of calibration;
6. identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

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7. maintain calibration records for inspection, measuring and test equipment (see 4.1.6);
8. assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;
9. ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;
10. ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;
11. safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

Calibration of inspection, measuring or test equipment services shall be conducted by a qualified laboratory. Commercial, independent calibration facilities shall be accredited to ISO/IEC Guide 25 with a scope which includes calibration of such equipment, or have evidence, e.g. second party assessment that they meet the intent of ISO/IEC Guide 25, e.g. traceability and professional competency.

Records (see 4.1.6) of the calibration activity for all gages, measuring and test equipment, including employee-owned gages, shall include:

- Revisions following changes as appropriate
- Gage conditions and actual readings as received for calibration
- Notification to the customer if nonconforming material has been shipped.

4.1.4.7 Supplier Laboratory Requirements

Where inspection, testing and calibration services are conducted by a laboratory facility, the laboratory shall comply with ISO/IEC Guide 25.

NOTE: Not all inspection and testing will need to be conducted in a laboratory facility.

4.1.4.8 Revalidation**ISO 9004 Quality Management****4.1.4.7 Supplier Laboratory Requirements****4.1.4.8 Revalidation**

Periodic revalidation shall be performed to ensure that the product and/or service continues to meet the customer needs and conforms to the product and/or service specification.

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Revalidation shall be planned and documented, and should include considerations of actual field experience, impact of personnel changes, adequacy of procedures, instructions, guides and proposed modifications.

4.1.5 Customer Satisfaction Measures

To ensure that the product and/or service is fit for customer use, the organisation shall have a documented procedure for the determination, continual monitoring and feedback of customer satisfaction and dissatisfaction at appropriate stages of product/service realisation. The organisation shall specify the measures to be used, the frequency of review, customer satisfaction improvement goals, and how objectivity and validity are assured. The effectiveness of measures implemented shall be periodically re-evaluated. These measures, including revisions, shall be approved by authorised personnel.

The organisation shall establish and document customer satisfaction goals to meet current and future customer expectations. These goals, and plans to achieve the goals, should be based on

1. analysis of competitive products and/or services
2. on benchmarking inside and outside the organisation's commodity and industry.

The organisation shall analyse the results of the customer satisfaction measures on a continual basis to take appropriate action. A summary of these results shall be provided for the management review process. Trends in customer satisfaction and customer dissatisfaction shall be documented and compared to relevant market data.

NOTE: Organisations should compare customer satisfaction results to those of competitors, or appropriate benchmarks.

NOTE: Consideration should be given to internal, external and final customers.

4.1.6 Analysis of Data (including records)

The organisation shall effectively analyse data, including quality records, to provide information to ensure effectiveness of the quality management system and demonstration of

4.1.5 Customer Satisfaction Measures

The organisation's system for determination, monitoring and feedback of customer satisfaction, and dissatisfaction, should address quality, service and price for value provided on a continual basis.

The organisation should establish procedures for planning and implementing appropriate market activities to more efficiently obtain the "voice of the customer". Elements associated with quality in marketing should include:

1. complementary services
2. competitor activities and performances
3. review of legislation (e.g. health, safety and environmental) and relevant national and international standards and codes
4. analysis and review of customer requirements, service data and contract information that has been collected (relevant summaries of the analysed data should be communicated to the appropriate personnel, such as manufacturing, purchasing, design or delivery)
5. consultation with all affected organisation functions to confirm their commitment and ability to meet specified requirements
6. ongoing research to examine changing market needs, new technology and the impact of competition
7. new products and new process technology

In order to define customer satisfaction and dissatisfaction levels, the organisation should consider the various data collection methods. The organisation should define the best data collection methods in accordance with the nature of the study, deadlines, current technology and available funds.

4.1.6 Analysis of Data (including records)

The organisation should have a documented procedure to analyse the effective and efficient use of information and data in order to assess progress relative to plans, goals, and organisational

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conformance to specified requirements.

The collection of data shall be planned and gathered from various sources including reports and records from internal audits, corrective action, nonconforming product, customer complaints, surveys, benchmarking, operations, sales, field service, suppliers and other relevant sources.

The organisation shall identify the need for statistical techniques required for analysing and verifying process capability and product characteristics, and implement appropriate techniques for the analysis of data. Analysis shall be based on the system, process and product measures, including quality records.

Information based upon the analysis of data shall be communicated to the organisation's management for prompt action as appropriate.

The organisation shall establish and maintain documented procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records to demonstrate conformance to specified requirements.

Quality records shall be legible, and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer, or the customer's representative for an agreed period.

4.2 Improvement

4.2.1 Corrective Action

The organisation shall establish and maintain documented procedures for eliminating the causes of nonconformity, defect or other undesirable situation in quality characteristics and quality system to prevent recurrence.

The organisation shall review the

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performance, and to identify areas for improvement. In analysis the overall performance should be divided into its parts to find out their nature and relationships to produce information for management decisions.

The organisation should document how performance information and data from all parts of the organisation are integrated and analyzed to assess overall organisational performance in key areas. Information and data should be used to determine

1. customer-related performance,
2. operational performance, including human resource and product/service performance,
3. competitive performance
4. economics of quality, financial and market-related performance.

Information and data from all parts of the organisation should be integrated and analysed to assess overall organisational performance in major areas. Analysis should have a strategic viewpoint covering the whole management system consisting of the major organisational processes, as well as an operational viewpoint, particularly considering significant processes.

Organisational performance should be analysed systematically for strategic planning and goal setting. Analysis should draw upon all types of facts providing data and information on customer-related performance, operational performance including product performance, and financial and market-related performance. Also competitive aspects to own targets, competitors' performance and relevant benchmarks should be considered in analysis. This information should be incorporated into the organisation's business or strategic plans, as appropriate.

Where technical analysis is performed by laboratories, the laboratories should comply with ISO/IEC Guide 25.

4.2 Improvement

4.2.1 Corrective Action

To implement corrective action evaluations, management should establish and maintain an information system for the collection and dissemination of data (see 4.1.6) from all relevant sources. Management should assign responsibilities for the information system and for service quality improvement.

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nonconformance reports, customer complaints and other relevant quality system records and take prompt corrective action, as appropriate.

Responsibilities for corrective action steps shall be defined and the procedures for corrective action shall require use of a disciplined problem solving process to include:

- a) the effective handling of customer complaints and product nonconformity reports,
- b) immediate containment of nonconforming product, including disposition of nonconforming material (see 3.3.5), while investigating the cause of nonconformity,
- c) investigation of the root cause of nonconformity's relating to product and/or service, process and quality system, and recording the results of the investigation,
- d) identification of the corrective action needed to eliminate the cause of nonconformities (see 4.1.6),
- e) evaluation (see 4.1.6) to determine the effects on the in-process or final products or services, and other product and/or service offerings, as appropriate, and to what extent reprocessing, retesting, recalibration or other actions that may be necessary.
- f) application of remedies to ensure that corrective action is taken and that it is effective
- g) implementation of corrective action for product and/or service already delivered, but subsequently discovered to be nonconforming, including notification to customers where possible.

NOTE: Application of corrective actions can result in changes to production, packing, service, transit or storage processes, a product or service specification and/or revision of the quality system.

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The significance of a problem affecting quality should be evaluated in terms of its potential impact on such aspects as processing costs, quality-related costs, performance, dependability, safety and customer satisfaction. Appropriate organisational functions, e.g. marketing, purchasing, human resources, should be represented in the corrective action process.

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The organisation shall record the results of the evaluation, and revise quality system documentation (see 1.5 and 3.1.4) and records (see 4.1.6) to reflect corrective actions taken as appropriate. . . Corrective action information shall be submitted to management review.

4.2.2 Preventive Action

The organisation shall establish and maintain documented procedures for implementing preventive action to detect, analyse and eliminate the causes of potential nonconformities in the quality system, products, or processes to prevent their occurrence.

Measures necessary for the early warning of out-of-control operating conditions of the (production) process shall be identified and implemented. The organisation shall review the customer satisfaction results, audit results, records from processes, e.g. failure mode and effects analysis (FMEA) and work operations (see 4.1.6), and other relevant quality system records and take prompt preventive action, as appropriate.

Responsibilities for preventive action steps shall be defined and the procedures for preventive action shall require use of a disciplined problem solving process to include:

1. identification and selection of system, product or process risks to be addressed
2. identification of the preventive action needed to eliminate the occurrence of nonconformities (see 4.1.6), using appropriate product or process improvement tools, e.g. mistake-proofing,
3. evaluation (see 4.1.6) to determine the effects on the in-process or final products or services, and other product and/or service offerings, as appropriate, and to what extent other actions may be necessary.
4. application of remedies to ensure that preventive action is taken is effective.

The organisation shall record the results of the evaluation, and revise quality system documentation (see 1.5 and 3.1.4) and records (see 4.1.6) to reflect preventive actions taken as appropriate. Preventive action information shall be submitted to management review.

4.2.3 Improvement Processes

The organisation shall demonstrate continual

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4.2.2 Preventive Action

The organisation should use disciplined problem solving methods to identify the causes of potential nonconformities.

The significance of a potential problem affecting quality should be evaluated in terms of its potential impact on such aspects as processing costs, quality-related costs, performance, dependability, safety and customer satisfaction. Appropriate organisational functions, e.g. marketing, purchasing, human resources, should be represented in the corrective action process.

Preventive action to eliminate a potential nonconformity is not necessarily required for every potential nonconformity identified, but should be considered for improvement.

Management should ensure the implementation and application within a reasonable and defined period of time of preventive action.

Controls should be applied to ensure preventive action is effective and efficient.

4.2.3 Improvement Processes

The organisation shall continually improve in

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quality system improvement. A comprehensive continual improvement philosophy shall be fully deployed throughout the organisation and addressed in the Quality Policy (see 1.3).

The organisation shall have knowledge of appropriate measures and methodologies for continuous improvement, and use those that are appropriate for their products or services.

The organisation shall allocate appropriate resources for innovative quality improvements, based upon industry benchmarking and market data.

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quality, service and value provided to customers. Suppliers should develop specific action plans for continuous improvement in processes that are most important to the customer once those processes have demonstrated stability and acceptable capability.

Based upon industry benchmarking and market data, the organisation shall allocate appropriate resources to innovative organisational improvements.