

**4.0 QUALITY MANAGEMENT SYSTEM**

**4.1 General requirements**

Has the organisation established, documented, implemented and maintained a quality management system and Continually improve its effectiveness in accordance with the requirements of this International Standard? Yes

Does the organisation:

- a) identify the processes needed for the quality management system and their application throughout the organisation? Yes
- b) determine the sequence and interaction of these processes? Yes
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective? Yes
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes? Yes
- e) monitor, measure and analyse these processes and implement actions necessary to achieve planned results and continual improvement of these processes? Yes

Are these processes managed by the organisation in accordance with the requirements of this International Standard? Yes

Where an organisation chooses to outsource any process that affects product conformity with requirements, does the organisation ensure control over such processes? Yes

Is the control of such outsource processes identified within the quality management system? Yes

**4.2 Documentation requirements**

**4.2.1 General**

Does the quality management system documentation include:

- a) documented statements of a quality policy and quality objectives? Yes
- b) a quality manual? Yes
- c) documented procedures required by this International Standard? Yes
- d) documents needed by the organisation to ensure the effective planning, operation and control of its processes? Yes
- e) records required by this International Standard (see 4.2.4)? and Yes
- f) quality system requirements imposed by the applicable Regulatory Authorities? Yes

Does the organisation ensure that personnel have access to quality management system documentation and are aware of relevant procedures ? Yes

Do Customer and/or regulatory authority representatives have access to quality management system documentation ? Yes

**4.2.2 Quality manual**

Has the organisation established and maintained a quality manual that includes:

- a) the scope of the quality management system, including details of, and justification for, any exclusions? Yes
- b) the documented procedures established for the quality management system, or reference to them, and when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown? Yes
- c) a description of the interaction between the processes of the quality management system? Yes

**4.2.3 Control of documents**

- Are the documents required by the quality management system controlled? Yes
- Are records controlled according to the requirements given in 4.2.4? Yes
- Has a documented procedure been established to define the controls needed to:
  - a) approve documents for adequacy prior to issue? Yes
  - b) review and update as necessary and re-approve documents? Yes
  - c) ensure that changes and the current revision status of documents are identified? Yes
  - d) ensure that relevant versions of applicable documents are available at points of use? Yes
  - e) ensure that documents remain legible and readily identifiable? Yes
  - f) ensure that documents of external origin are identified and their distribution controlled and prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? Yes
- Does the organisation co-ordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements? Yes

**4.2.4 Control of records**

- Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system? Yes
- Do records remain legible, readily identifiable and retrievable? Yes
- Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records? Yes
- Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers? Yes
- Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements? Yes

**4.3 Configuration management**

- Has the organisation established, documented and maintained a configuration management process appropriate to the product? Yes

**5.0 MANAGEMENT RESPONSIBILITY**

**5.1 Management commitment**

- Has Top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:
  - a) communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements? Yes
  - b) establishing the quality policy? Yes
  - c) ensuring that quality objectives are established? Yes
  - d) conducting management reviews and ensuring the availability of resources? Yes

**5.2 Customer focus**

- Has Top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)? Yes

**5.3 Quality policy**

Has Top management ensured that the quality policy:

- a) is appropriate to the purpose of the organisation? Yes
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system? Yes
- c) provides a framework for establishing and reviewing quality objectives? Yes
- d) is communicated and understood within the organisation and is reviewed for continuing suitability? Yes

**5.4 Planning**

**5.4.1 Quality objectives**

Has Top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organisation? Yes

Are the quality objectives measurable and consistent with the quality policy? Yes

**5.4.2 Quality management system planning**

Has Top management ensured that:

- a) the planning of the quality management system is carried out in order to meet the requirements (see 4.1), as well as the quality objectives? Yes
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? Yes

**5.5 Responsibility, authority and communication**

**5.5.1 Responsibility and authority**

Has Top management ensured that the responsibilities and authorities are defined and communicated within the organisation? Yes

**5.5.2 Management representative**

Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

- a) ensuring that processes needed for the quality management system are established, implemented and maintained? Yes
- b) reporting to top management on the performance of the quality management system and any need for improvement? Yes  
ensuring the promotion of awareness of customer requirements throughout the organisation and the organisational freedom to resolve matters pertaining to quality? Yes

**5.5.3 Internal communication**

Has Top management ensured that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality management system? Yes

**5.6 Management review**

**5.6.1 General**

Has Top management reviewed the organisation's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness? Yes

Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives? Yes

Are records from management reviews maintained (see 4.2.4)? Yes

**5.6.2 Review input**

Does the input to management review include information on:

- a) results of audits? Yes
- b) customer feedback? Yes
- c) process performance and product conformity? Yes
  
- d) status of preventive and corrective actions? Yes
- e) follow-up actions from previous management reviews? Yes
- f) changes that could affect the quality management system and make recommendations for improvement? Yes

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- f) changes that could affect the quality management system and make recommendations for improvement? Yes

**5.6.3 Review output**

Does the output from the management review include any decisions and actions related to:

- a) improvement of the effectiveness of the quality management system and its processes? Yes
- b) improvement of product related to customer requirements and resource needs? Yes

**6.0 RESOURCE MANAGEMENT**

**6.1 Provision of resources**

Has the organisation determined and provided the resources needed:

- a) to implement and maintain the quality management system and continually improve its effectiveness? Yes
- b) to enhance customer satisfaction by meeting customer requirements? Yes

**6.2 Human resources**

**6.2.1 General**

Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience? Yes

**6.2.2 Competence, awareness and training**

Does the organisation:

- a) determine the necessary competence for personnel performing work affecting product quality? Yes
- b) provide training or take other actions to satisfy these needs? Yes
- c) Evaluate the effectiveness of the actions taken? Yes
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? Yes
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4)? Yes

**6.3 Infrastructure**

Does the organisation determine, provide and maintain the infrastructure needed to achieve conformity to product requirements?

Does the infrastructure includes, as applicable :

- a) buildings, workspace and associated utilities? Yes
- b) process equipment (both hardware and software)? Yes
- c) supporting services (such as transport or communication)? Yes

**6.4 Work environment**

Does the organisation determine and manage the work environment needed to achieve conformity to product requirements? Yes

**7.0 PRODUCT REALIZATION**

**7.1 Planning of product realisation**

Does the organisation plan and develop the processes needed for product realisation ? (see 4.1) Yes

Is planning of product realisation consistent with the requirements of the other processes of the quality management system (see 4.1)? Yes

In planning product realisation, does the organisation determine the following, as appropriate:

- a) quality objectives and requirements for the product? Yes
  - b) the need to establish processes, documents, and provide resources specific to the product? Yes
  - c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance? Yes
  - d) records needed to provide evidence that the realisation processes and resulting product meet requirements (see 4.2.4)? Yes
  - e) the identification of resources to support operation and maintenance of the product? Yes
- Is the output of this planning in a form suitable for the organisation's method of operations? Yes

**7.2 Customer-related processes**

**7.2.1 Determination of requirements related to the product**

Does the organisation determine:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities? Yes
- b) requirements not stated by the customer but necessary for specified or intended use, where known? Yes
- c) statutory and regulatory requirements related to the product? Yes
- d) any additional requirements determined by the organisation? Yes

**7.2.2 Review of requirements related to the product**

Does the organisation review the requirements related to the product? Yes

Is the review conducted prior to the organisation's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that:

- a) product requirements are defined? Yes
- b) contract or order requirements differing from those previously expressed are resolved? Yes
- c) the organisation has the ability to meet the defined requirements? Yes

d) risks (e.g., new technology, short delivery time scale) have been evaluated? Yes

Are records of the results of the review and actions arising from the review maintained (see 4.2.4)? Yes

Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organisation before acceptance? Yes

Where product requirements are changed, does the organisation ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements? Yes

**7.2.3 Customer communication**

Does the organisation determine and implement effective arrangements for communicating with customers in relation to:

- a) product information? Yes
- b) inquiries, contracts or order handling, including amendments? Yes
- c) customer feedback, including customer complaints? Yes

**7.3 Design and development**

**7.3.1 Design and development planning**

Does the organisation plan and control the design and development of product? Yes

During the design and development planning, does the organisation determine:

- a) the design and development stages in respect of organisation, task sequence, mandatory steps, significant stages and method of configuration control? Yes
- b) the review, verification and validation that are appropriate to each design and development stage? and
- c) the responsibilities and authorities for design and development? Yes

Where appropriate, due to complexity, does the organisation give consideration to the following activities:

- a) structuring the design effort into significant elements for each element, analysing the tasks and the necessary resources for its design and development? Yes
- b) Does this analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements? Yes

Does the organisation manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility? Yes

Is planning output updated, as appropriate, as the design and development progresses? Yes

Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements? Yes

**7.3.2 Design and development inputs**

Are inputs relating to product requirements determined and are records maintained (see 4.2.4) and do these inputs include:

- a) functional and performance requirements? Yes
- b) applicable statutory and regulatory requirement ? Yes
- c) where applicable, information derived from previous similar designs? Yes
- d) other requirements essential for design and development? Yes

Are these inputs reviewed for adequacy? Yes

Are requirements completed, unambiguous and not in conflict with each other? Yes

**7.3.3 Design and development outputs**

Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release? Yes

Do the design and development outputs:

- a) meet the input requirements for design and development? Yes
- b) provide appropriate information for purchasing, production and for service provision? Yes
- c) contain or reference product acceptance criteria? Yes
- d) specify the characteristics of the product that are essential for its safe and proper use? And Yes
- e) identify key characteristics, when applicable, in accordance with design or contract requirements? Yes

Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organisation; for example:

- a) drawings, part lists, specifications? Yes
- b) a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product? Yes
- c) information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product? Yes

**7.3.4 Design and development review**

At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to (1):

- a) evaluate the ability of the results of Design and development to meet requirements? Yes
- b) identify any problems and propose necessary actions? Yes
- c) authorise progression to the next stage? Yes

Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed? Yes

Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)? Yes

**7.3.5 Design and development verification**

Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements? Yes

Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)? Yes

**7.3.6 Design and development validation**

Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known? Yes

Wherever practicable, is validation completed prior to the delivery or implementation of the Product? Yes

Are records of the results of validation and any necessary actions maintained (see 4.2.4)? Yes

**7.3.6.1 Documentation of design and/or development verification and validation**

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

**7.3.6.2 Design and/or development verification and validation testing**

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

- a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria? Yes
- b) test procedures describe the method of operation, the performance of the test, and the recording of the results? Yes
- c) the correct configuration standard of the product is submitted for the test? Yes
- d) the requirements of the test plan and the test procedures are observed? Yes
- e) the acceptance criteria are met? Yes

**7.3.7 Control of design and development changes**

Are design and development changes identified and records maintained? Yes

Are the changes reviewed, verified and validated, as appropriate, and approved before implementation? Yes

Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered? Yes

Does the organisation's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement? Yes

Records of the results of the review of changes and any necessary actions maintained (see 4.2.4)? Yes

**7.4 Purchasing**

**7.4.1 Purchasing process**

Does the organisation ensure that purchased product conforms to specified purchase Requirements? Yes

Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realisation or the final product? Yes

Is the organisation responsible for the quality of all products purchased from suppliers, including customer-designated sources? Yes

Does the organisation evaluate and select Suppliers based on their ability to supply product in accordance with the organisation's requirements? Yes

Are criteria for selection, evaluation and re-evaluation established? Yes

Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4)? Yes

Does the organisation:

- a) Maintain a register of approved Suppliers that includes the scope of the approval? Yes
- b) Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented? Yes
- c) Define the necessary actions to take when dealing with Suppliers that do not meet requirements? Yes
- d) Ensure where required that both the organisation and all Suppliers use customer-approved special process sources? Yes
- e) Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources? Yes

**7.4.2 Purchasing information**

Does purchasing information describe the product to be purchased, including where appropriate:

- a) requirements for approval of product, procedures, processes and equipment? Yes
- b) requirements for qualification of personnel? Yes
- c) quality management system requirements? Yes
- d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data? Yes
- e) requirements for design, test, examination, inspection and related instructions for acceptance by the Organisation? Yes
- f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing? Yes
- g) relative to supplier notification to Organisation of non-conforming product and arrangements for Organisation approval of supplier non-conforming material? Yes  
  - Yes
- h) requirements for the supplier to notify the Organisation of changes in product and/or process definition and, where required, obtain organisation approval? Yes
- i) right of access by the organisation, their customer, and authorities to all facilities involved in the order and to all applicable records? Yes
- j) requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required? Yes

Does the organisation ensure the adequacy of specified purchase requirements prior to their communication to the supplier? Yes

**7.4.3 Verification of purchased product**

Does the organisation establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification? Yes

Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure? Yes

Where the organisation utilises test reports to verify purchased product, is the data in those reports acceptable per applicable specifications? Yes

Does the organisation periodically validate test reports for raw material? Yes

Where the organisation delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained? Yes

Where the organisation or its customer intends to perform verification at the supplier's premises, does the organisation state the intended verification arrangements and method of product release in the purchasing information? Yes

Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organisation's premises that subcontracted product conforms to specified requirements? Yes

It is ensured that verification by the customer is not used by the organisation as evidence of effective control of quality by the supplier (it does not absolve the organisation of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer)? Yes

**7.5 Production and Service Provision**

**7.5.1 Control of production and service provision**

Does planning consider, as applicable:

- a) the establishment of process controls and development of control plans where key characteristics have been identified? Yes
- b) the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realisation? Yes
- c) the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics? Yes
- d) special processes? (see 7.5.2) Yes

Does the organisation plan and carry out production and service provision under controlled conditions. Yes

Do these controlled conditions include, as applicable:

- a) the availability of information that describes the characteristics of the product? Yes
- b) the availability of work instructions, as necessary? Yes
- c) the use of suitable equipment? Yes
- d) the availability and use of monitoring and measuring devices? Yes
- e) the implementation of monitoring and measurement? Yes
- f) the implementation of release, delivery and post-delivery activities? Yes
- g) accountability for all product during manufacture (e.g., parts quantities, split orders, non-conforming product)? Yes
- h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorised? Yes
- i) provision for the prevention, detection, and removal of foreign objects? Yes
- j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality? Yes
- k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)? Yes

**7.5.1.1 Production documentation**

Are production operations carried out in accordance with approved data? Yes

Does the data contain as necessary:

- a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveller, router, work order, process cards); and inspection documents (see 8.2.4.1)? Yes
- b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use? Yes

**7.5.1.2 Control of production process changes**

Are persons authorised to approve changes to production processes identified?	Yes
Has the organisation identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements?	Yes
Are changes affecting processes, production equipment, tools and programs documented?	Yes
Are procedures available to control their implementation?	Yes
Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality?	Yes

**7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs**

Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures?	Yes
Does validation prior to production use include verification of the first article produced to the design data/specification?	Yes
Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage?	Yes

**7.5.1.4 Control of work transferred, on a temporary basis, outside the organisation's facilities**

When planning to temporarily transfer work to a location outside the organisation's facilities, does the organisation define the process to control and validate the quality of the work?	Yes
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**7.5.1.5 Control of service operations**

Where servicing is a specified requirement, do service operation processes provide for:

a) a method of collecting and analysing in-service data?	Yes
b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements?	Yes
c) the control and updating of technical documentation?	Yes
d) the approval, control, and use of repair schemes? and,	Yes
e) the controls required for off-site work (e.g., organisation's work undertaken at the customer's facilities)?	Yes

**7.5.2 Validation of processes for production and service provision**

Does the organisation validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered)?	Yes
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**Note :These processes are frequently referred to as special processes.**

Does validation demonstrate the ability of these processes to achieve planned results?	Yes
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Has the organisation established arrangements for these processes including, as applicable:

a) defined criteria for review and approval of the processes?	Yes
b) qualification and approval of special processes prior to use?	Yes
c) approval of equipment and qualification of personnel?	Yes
d) use of specific methods and procedures?	Yes
e) control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto?	Yes
d) requirements for records (see 4.2.4)?	Yes
e) and revalidation?	Yes

**7.5.3 Identification and traceability**

Where appropriate, has the organisation identified the product by suitable means throughout product realisation?	Yes
Does the organisation maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration?	Yes
Has the organisation identified the product status with respect to monitoring and measurement requirements?	Yes
When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organisation establish and document controls for the media?	Yes
Where traceability is a requirement, does the organisation control and record the unique identification of the product? (see 4.2.4)	Yes
According to the level of traceability required by contract, regulatory, or other established requirement, does the organisation's system provide for:	
a) identification to be maintained throughout the product life?	Yes
b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch?	Yes
c) in any assembly, the identity of its components and those of the next higher assembly to be traced?	Yes
d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved?	Yes

**7.5.4 Customer property**

Does the organisation exercise care with customer property while it is under the organisation's control or being used by the organisation?	Yes
Has the organisation identified, verified, protected and safeguarded customer property provided for use or incorporation into the product?	Yes
Does the organisation define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer?	Yes

**7.5.5 Preservation of product**

Does the organisation preserve the conformity of product during internal processing and delivery to the intended destination?	Yes
Does the preservation include identification, handling, packaging, storage and protection?	Yes
Does preservation also apply to the constituent parts of a product?	Yes
Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for:	
a) cleaning?	Yes
b) prevention, detection and removal of foreign objects?	Yes
c) special handling for sensitive products?	Yes
d) marking and labelling including safety warnings?	Yes
e) shelf life control and stock rotation?	Yes
f) special handling for hazardous materials?	Yes
Does the organisation ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration?	Yes

**7.6 Control of monitoring and measuring devices**

Does the organisation determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements? (see 7.2.1) Yes

Does the organisation maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria? Yes

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

Does the organisation establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements? Yes

Does the organisation ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out? Yes

Where necessary to ensure valid results, is measuring equipment:

- a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded? Yes
- b) adjusted or re-adjusted as necessary? Yes
- c) identified to enable the calibration status to be determined? Yes
- d) safeguarded from adjustments that would invalidate the measurement result? Yes
- e) protected from damage and deterioration during handling, maintenance and storage? Yes
- f) recalled to a defined method when requiring calibration? Yes

Does the organisation assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements? Yes

Does the organisation take appropriate action on the equipment and any product affected? Yes

Are records of the results of calibration and verification maintained? (see 4.2.4) Yes

When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed? Yes

Is this undertaken prior to initial use and reconfirmed as necessary? Yes

**8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

**8.1 General**

Does the organisation plan and implement the monitoring, measurement, analysis and improvement processes needed (1) :

- a) to demonstrate conformity of the product? Yes
- b) to ensure conformity of the quality management system, and? Yes
- c) to continually improve the effectiveness of the quality management system? Yes

Does this include determination of applicable methods, including statistical techniques, and the extent of their use? Yes

**8.2.1 Customer satisfaction**

As one of the measurements of the performance of the quality management system, does the organisation monitor information relating to customer perception as to whether the organisation has met customer requirements? Yes

Are the methods for obtaining and using this information determined? Yes

**8.2.2 Internal audit**

Does the organisation conduct internal audits at planned intervals to determine whether the quality management system:  
 a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organisation? Yes

b) is effectively implemented and maintained? Yes

Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? Yes

Is the audit criteria, scope, frequency and methods defined? Yes

Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process? Yes

Does the organisation ensure internal auditors do not audit their own work? Yes

Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure? Yes

Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes? Yes

Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2)? Yes

Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements? Yes

Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organisation performance? Yes

Do internal audits also meet contract and/or regulatory requirements? Yes

**8.2.3 Monitoring and measurement of processes**

Does the organisation apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes? Yes

Do these methods demonstrate the ability of the processes to achieve planned results? Yes

When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product? Yes

- In the event of process nonconformity, does the organisation:
- a) take appropriate action to correct the non-conforming process? Yes
  - b) evaluate whether the process nonconformity has resulted in product nonconformity? Yes
  - c) identify and control the non-conforming product in accordance with clause 8.3? Yes

**8.2.4 Monitoring and measurement of product**

Does the organisation monitor and measure the characteristics of the product to verify that product requirements have been met?	Yes
Is this carried out at appropriate stages of the product realisation process in accordance with the planned arrangements? (see 7.1)	Yes
When key characteristics have been identified, are they monitored and controlled?	Yes
When the organisation uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use?	Yes
Does the plan preclude the acceptance of lots whose samples have known non-conformities?	Yes
When required, is the plan submitted for customer approval?	Yes
Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities?	Yes
Is evidence of conformity with the acceptance criteria maintained?	Yes
Do records indicate the person(s) authorising release of product? (see 4.2.4)	Yes
Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?	Yes

**8.2.4.1 Inspection documentation**

Are measurement requirements for product or service acceptance documented?	Yes
Does this documentation, which may be part of the production documentation, include :	
a) Criteria for acceptance and/or rejection?	Yes
b) Where in the sequence measurement and testing operations are performed?	Yes
c) a record of the measurement results and type of measurement instruments required and any specific instructions associated with their use?	Yes
Do test records show actual test results data when required by the specification or acceptance test plan?	Yes
When required to demonstrate product qualification does the organisation ensure that records provide evidence that the product meets the defined requirements?	Yes

**8.2.4.2 First Article Inspection**

Does the organisation's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result?	Yes
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**8.3 Control of non-conforming product**

Does the organisation ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery?	Yes
Are the controls and related responsibilities and authorities for dealing with non-conforming product defined in a documented procedure?	Yes
Does the organisation's documented procedure define the responsibility for review and authority for the disposition of non-conforming product and the process for approving personnel making these decisions?	Yes

Does the organisation deal with non-conforming product in one or more of the following ways by:

- a) taking action to eliminate the detected nonconformity? Yes
- b) authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer? Yes
- c) taking action to preclude its original intended use or application? Yes

Are records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, Maintained? (see 4.2.4) Yes

When non-conforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements? Yes

When non-conforming product is detected after delivery or use has started, does the organisation take action appropriate to the effects, or potential effects, of the nonconformity? Yes

In addition to any contract or regulatory authority reporting requirements, does the organisation's system provide for timely reporting of delivered non-conforming product that may affect reliability or safety? Yes

Does notification include a clear description of the nonconformity, which includes as necessary, parts affected, customer and/or organisation part numbers, quantity, and date(s) delivered? Yes

**8.4 Analysis of data**

Does the organisation determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality

management system can be made? Yes

Does this include data generated as a result of monitoring and measurement and from other relevant sources? Yes

Does the analysis of data provide information relating to:

- a) customer satisfaction (see 8.2.1)? Yes
- b) conformity to product requirements (see 7.2.1)? Yes
- c) characteristics and trends of processes and products including opportunities for preventive action? And Yes
- d) suppliers? Yes

**8.5 Improvement**

**8.5.1 Continual improvement**

Does the organisation continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review? Yes

**8.5.2 Corrective action**

Does the organisation take action to eliminate the cause of non-conformities in order to prevent recurrence? Yes

Are Corrective actions appropriate to the effects of the non-conformities encountered? Yes

Is a documented procedure established to define requirements for:

- a) reviewing non-conformities (including customer complaints)? Yes
- b) determining the causes of non-conformities? Yes
- c) evaluating the need for action to ensure that non-conformities do not recur? Yes
- d) determining and implementing action needed? Yes
- e) recording of the results of the action taken (see 4.2.4)? Yes

- |   |     |
|---|-----|
| f) reviewing corrective action taken?   | Yes |
| g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause? | Yes |
| h) specific actions where timely and/or effective corrective actions are not achieved?  | Yes |

**8.5.3 Preventive action**

Does the organisation determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence? Yes

Are preventive actions appropriate to the effects of the potential problems? Yes

Is a documented procedure established to define requirements for:

- |  |     |
|--|-----|
| a) determining potential non-conformities and their causes?                  | Yes |
| b) evaluating the need for action to prevent occurrence of non-conformities? | Yes |
| c) determining and implementing action needed?                               | Yes |
| d) recording of the results of the action taken (see 4.2.4)?                 | Yes |
| e) reviewing preventive action taken?  | Yes |