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AEROSPACE STANDARD

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Superseding AS9100

Quality Systems - Aerospace - Model for Quality Assurance in Design, Development, Production, Installation and Servicing

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FOREWORD

To assure customer satisfaction, aerospace industry organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the aerospace industry, and the resulting diversity of regional/national requirements and expectations, has complicated this objective. End-product organizations face the challenge of assuring the quality of, and integrating, product purchased from suppliers throughout the world and at all levels within the supply chain. Aerospace suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

This document standardizes, to the greatest extent possible, quality management system requirements for the aerospace industry. The establishment of common requirements, for use at all levels of the supply-chain, by organizations around the world, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.

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STRUCTURE AND APPLICATION

This standard includes aerospace requirements applied to, and integrated with, both the ISO 9001:2000 and the ISO 9001:1994 quality management system models. The section of this standard that shall apply is determined by the organization's current quality management system (QMS) status in regards to alignment/compliance with ISO 9001.

Organizations now having a QMS based on ISO 9001:1994, that are expanding the scope of their QMS to include AS9100 requirements, shall utilize the section of this standard aligned with ISO 9001:1994. Upon transition to an ISO 9001:2000-based QMS, organizations shall use the section of this standard aligned with ISO 9001:2000. In accordance with the time period established for organizations to transition from ISO 9001:1994 to ISO 9001:2000, the section of this standard based on the ISO 9001:1994 model will be withdrawn on December 15, 2003.

Organizations initially developing an ISO 9001/AS9100-based QMS after December 15, 2000 must develop a QMS based on ISO 9001:2000 and shall utilize the section of this standard that is based on ISO 9001:2000.

The ISO 9001 model, and the corresponding AS9100 section, that is deployed shall be declared in the organization's quality manual.

SECTION 1 - QUALITY MANAGEMENT SYSTEMS - AEROSPACE - REQUIREMENTS
BASED ON ISO 9001:2000

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INTRODUCTION

General:

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

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

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

Process Approach:

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of:

a. understanding and meeting requirements,
b. the need to consider processes in terms of added value,
c. obtaining results of process performance and effectiveness, and
d. continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE: In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

Plan: establish theh objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

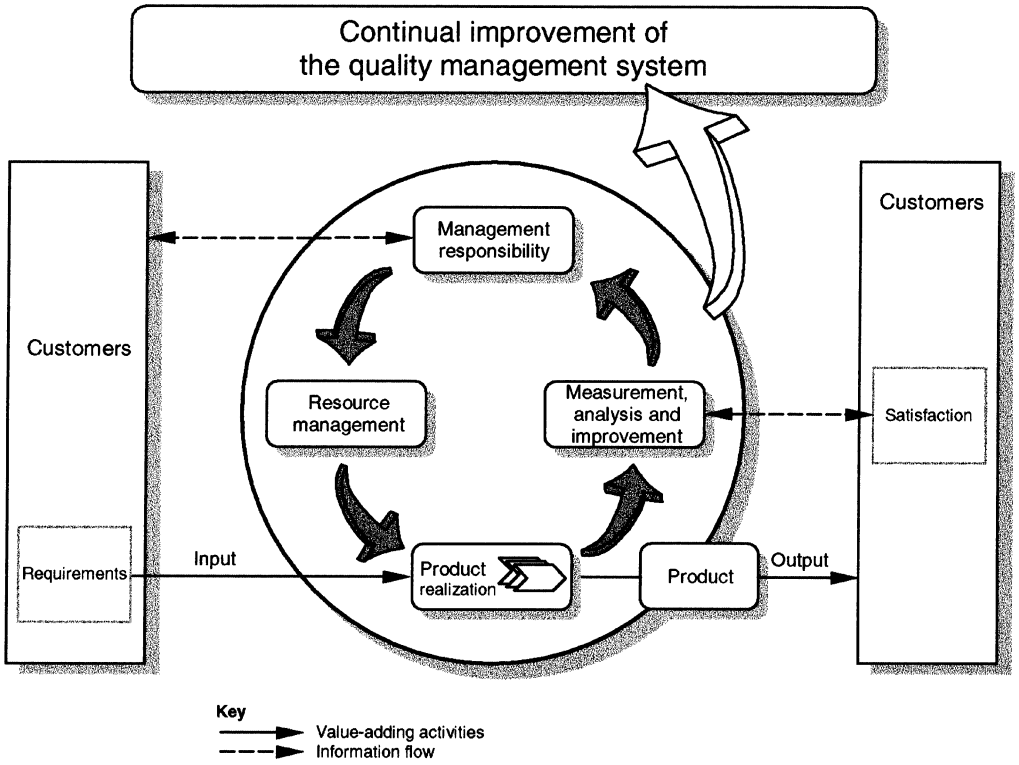

FIGURE 1 - Model of a Process-Based Quality Management System

1. SCOPE:

1.1 General:

This standard includes ISO 9001:2000[1] quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry. The additional aerospace requirements are shown in bold, italic text.

It is emphasized that the quality management system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.

This International Standard specifies requirements for a quality management system where an organization

a. needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b. aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application:

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

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[1] With the permission of the International Organization for Standardization (ISO). The complete standard may be obtained from any ISO member or from the ISO Central Secretariat, Case Postale 56, 1211 Geneva 20, SWITZERLAND. Copyright remains with ISO.

2. NORMATIVE REFERENCE:

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO ***(International Organization for Standardization)*** and IEC ***(International Electrotechnical Commission)*** maintain registers of currently valid International Standards.

ISO 9000:2000, Quality management systems - Fundamentals and vocabulary.

3. TERMS AND DEFINITIONS:

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

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → organization → customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

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

Key Characteristics: The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

4. QUALITY MANAGEMENT SYSTEM:

4.1 General Requirements:

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

The organization shall

a. identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b. determine the sequence and interaction of these processes,

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

d. ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e. monitor, measure and analyse these processes, and

f. implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation Requirements:

4.2.1 General: The quality management system documentation shall include

a. documented statements of a quality policy and quality objectives,

b. a quality manual,

c. documented procedures required by this International Standard,

d. documents needed by the organization to ensure the effective planning, operation and control of its processes,

e. records required by this International Standard (see 4.2.4), ***and***

f. quality system requirements imposed by the applicable regulatory authorities.

The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a. the size of organization and type of activities,
b. the complexity of processes and their interactions, and
c. the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality Manual: The organization shall establish and maintain a quality manual that includes

a. the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b. the documented procedures established for the quality management system, or reference to them, and

- ***when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.***

c. a description of the interaction between the processes of the quality management system.

4.2.3 Control of Documents: Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a. to approve documents for adequacy prior to issue,

b. to review and update as necessary and re-approve documents,

c. to ensure that changes and the current revision status of documents are identified,

d. to ensure that relevant versions of applicable documents are available at points of use,

e. to ensure that documents remain legible and readily identifiable,

f. to ensure that documents of external origin are identified and their distribution controlled, and

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

The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

4.2.4 Control of Records: Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

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

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

4.3 Configuration Management:

The organization shall establish, document and maintain a configuration management process appropriate to the product.

NOTE Guidance on configuration management is given in ISO 10007.

5. MANAGEMENT RESPONSIBILITY:

5.1 Management Commitment:

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a. communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b. establishing the quality policy,

c. ensuring that quality objectives are established,

d. conducting management reviews, and

e. ensuring the availability of resources.

5.2 Customer Focus:

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality Policy:

Top management shall ensure that the quality policy

a. is appropriate to the purpose of the organization,

b. includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c. provides a framework for establishing and reviewing quality objectives,

d. is communicated and understood within the organization, and

e. is reviewed for continuing suitability.

5.4 Planning:

5.4.1 Quality Objectives: Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning: Top management shall ensure that

a. the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b. the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority: Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management Representative: Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a. ensuring that processes needed for the quality management system are established, implemented and maintained,

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

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

d. the organizational freedom to resolve matters pertaining to quality.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

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

5.6 Management Review:

5.6.1 General: Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review Input: The input to management review shall include information on

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

5.6.3 Review Output: The output from the management review shall include any decisions and actions related to

a. improvement of the effectiveness of the quality management system and its processes,
b. improvement of product related to customer requirements, and
c. resource needs.

6. RESOURCE MANAGEMENT:

6.1 Provision of Resources:

The organization shall determine and provide the resources needed

a. to implement and maintain the quality management system and continually improve its effectiveness, and

b. to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources:

6.2.1 General: Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training: The organization shall

a. determine the necessary competence for personnel performing work affecting product quality,

b. provide training or take other actions to satisfy these needs,

c. evaluate the effectiveness of the actions taken,

d. ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,

e. maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure:

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

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

6.4 Work Environment:

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

NOTE Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

7. PRODUCT REALIZATION:

7.1 Planning of Product Realization:

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

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

a. quality objectives and requirements for the product;

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

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

d. records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);

e. the identification of resources to support operation and maintenance of the product.

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

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-Related Processes:

7.2.1 Determination of Requirements Related to the Product: The organization shall determine

a. requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b. requirements not stated by the customer but necessary for specified or intended use, where known,

c. statutory and regulatory requirements related to the product, and

d. any additional requirements determined by the organization.

7.2.2 Review of Requirements Related to the Product: The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a. product requirements are defined,
b. contract or order requirements differing from those previously expressed are resolved,
c. the organization has the ability to meet the defined requirements, ***and***
d. risks (e.g., new technology, short delivery time scale) have been evaluated.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

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

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer Communication: The organization shall determine and implement effective arrangements for communicating with customers in relation to

a. product information,
b. enquiries, contracts or order handling, including amendments, and
c. customer feedback, including customer complaints.

7.3 Design and Development:

7.3.1 Design and Development Planning: The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a. the design and development stages,

- in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,

b. the review, verification and validation that are appropriate to each design and development stage, and

c. the responsibilities and authorities for design and development.

Where appropriate, due to complexity, the organization shall give consideration to the following activities:

- structuring the design effort into significant elements;

- for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.

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

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

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

7.3.2 Design and Development Inputs: Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

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

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs: The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a. meet the input requirements for design and development,

b. provide appropriate information for purchasing, production and for service provision,

c. contain or reference product acceptance criteria,

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

e. identify key characteristics, when applicable, in accordance with design or contract requirements.

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the organization; for example:

- drawings, part lists, specifications;

- a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product;

- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

7.3.4 Design and Development Review: At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a. to evaluate the ability of the results of design and development to meet requirements,
b. to identify any problems and propose necessary actions, ***and***
c. to authorize progression to the next stage.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and Development Verification: Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

NOTE Design and/or development verification may include activities such as:

- ***performing alternative calculations,***
- ***comparing the new design with a similar proven design, if available,***
- ***undertaking tests and demonstrations, and***
- ***reviewing the design stage documents before release.***

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

NOTES

- ***Design and/or development validation follows successful design and/or development verification.***
- ***Validation is normally performed under defined operating conditions.***
- ***Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.***
- ***Multiple validations may be performed if there are different intended uses.***

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

7.3.6.2 Design and/or Development Verification and Validation Testing: Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

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

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

c. the correct configuration standard of the product is submitted for the test;

d. the requirements of the test plan and the test procedures are observed;

e. the acceptance criteria are met.

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

The organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing:

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

The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

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

The organization shall:

a. maintain a register of approved suppliers that includes the scope of the approval;

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

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

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

e. ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

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

a. requirements for approval of product, procedures, processes and equipment,

b. requirements for qualification of personnel,

c. quality management system requirements,

d. the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,

e. requirements for design, test, examination, inspection and related instructions for acceptance by the organization,

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

g. requirements relative to

- supplier notification to organization of nonconforming product and
- arrangements for organization approval of supplier nonconforming material,

h. requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,

i. right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and

j. requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product: The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification activities may include

a. obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),

b. inspection and audit at supplier's premises,

c. review of the required documentation,

d. inspection of products upon receipt, and

e. delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.

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

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

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.

Verification by the customer shall not be used by the organization as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

7.5 Production and Service Provision:

7.5.1 Control of Production and Service Provision: ***Planning shall consider, as applicable,***

- ***the establishment of process controls and development of control plans where key characteristics have been identified,***

- ***the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,***

- ***the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and***

- ***special processes (see 7.5.2).***

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a. the availability of information that describes the characteristics of the product,

b. the availability of work instructions, as necessary,

c. the use of suitable equipment,

d. the availability and use of monitoring and measuring devices,

e. the implementation of monitoring and measurement,

f. the implementation of release, delivery and post-delivery activities,

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

h. evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,

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

j. monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and

k. criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

7.5.1.1 Production Documentation: Production operations shall be carried out in accordance with approved data. This data shall contain as necessary

a. drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1), and

b. a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.

7.5.1.2 Control of Production Process Changes: Persons authorized to approve changes to production processes shall be identified.

The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.

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

7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs: Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.

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

7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities: When planning to temporarily transfer work to a location outside the organization's facilities, the organization shall define the process to control and validate the quality of the work.

7.5.1.5 Control of Service Operations: Where servicing is a specified requirement, service operation processes shall provide for

a. a method of collecting and analyzing in-service data,

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,

c. the control and updating of technical documentation,

d. the approval, control, and use of repair schemes, and

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

7.5.2 Validation of Processes for Production and Service Provision: The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

NOTE These processes are frequently referred to as special processes.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a. defined criteria for review and approval of the processes,

- qualification and approval of special processes prior to use,

b. approval of equipment and qualification of personnel,

c. use of specific methods and procedures,

- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,

d. requirements for records (see 4.2.4), and

e. revalidation.

7.5.3 Identification and Traceability: Where appropriate, the organization shall identify the product by suitable means throughout product realization.

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

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

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

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

According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:

a. identification to be maintained throughout the product life;

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;

c. for an assembly, the identity of its components and those of the next higher assembly to be traced;

d. for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained ***(see 4.3)***.

7.5.4 Customer Property: The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property***, including customer furnished data used for design, production and/or inspection.***

7.5.5 Preservation of Product: The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

a. cleaning;
b. prevention, detection and removal of foreign objects;
c. special handling for sensitive products;
d. marking and labeling including safety warnings;
e. shelf life control and stock rotation;
f. special handling for hazardous materials.

The organization shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of Monitoring and Measuring Devices:

The organization shall 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).

The organization shall 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.

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.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

7.6 (Continued):

Where necessary to ensure valid results, measuring equipment shall

a. be 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;

b. be adjusted or re-adjusted as necessary;

c. be identified to enable the calibration status to be determined;

d. be safeguarded from adjustments that would invalidate the measurement result;

e. be protected from damage and deterioration during handling, maintenance and storage;

f. be recalled to a defined method when requiring calibration.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT:

8.1 General:

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a. to demonstrate conformity of the product,
b. to ensure conformity of the quality management system, and
c. to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.1 (Continued):

NOTE

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

- ***design verification (e.g., reliability, maintainability, safety);***
- ***process control:***
  - ***selection and inspection of key characteristics;***
  - ***process capability measurements;***
  - ***statistical process control;***
  - ***design of experiment;***
- ***inspection - matching sampling rate to the criticality of the product and to the process capability;***
- ***failure mode and effect analysis.***

8.2 Monitoring and Measurement:

8.2.1 Customer Satisfaction: As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

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

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

b. is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

8.2.2 (Continued):

Detailed tools and techniques shall be developed such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits shall also meet contract and/or regulatory requirements.

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.3 Monitoring and Measurement of Processes: The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

In the event of process nonconformity, the organization shall

a. take appropriate action to correct the nonconforming process,
b. evaluate whether the process nonconformity has resulted in product nonconformity, and
c. identify and control the nonconforming product in accordance with clause 8.3.

8.2.4 Monitoring and Measurement of Product: The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

When key characteristics have been identified, they shall be monitored and controlled.

When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.

Product shall not be used 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.

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed 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.

8.2.4.1 Inspection Documentation: Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include

a. criteria for acceptance and/or rejection,

b. where in the sequence measurement and testing operations are performed,

c. a record of the measurement results, and

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

Test records shall show actual test results data when required by specification or acceptance test plan.

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

8.2.4.2 First Article Inspection: The organization's system shall 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.

NOTE See (AS) (EN) (SJAC) 9102 for guidance.

8.3 Control of Nonconforming Product:

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

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

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

8.3 (Continued):

The organization shall deal with nonconforming product by one or more of the following ways:

a. by taking action to eliminate the detected nonconformity;

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

c. by taking action to preclude its original intended use or application.

The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

- the product is produced to customer design, or
- the nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, the organization's system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

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

8.4 Analysis of Data:

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a. customer satisfaction (see 8.2.1),

b. conformity to product requirements (see 7.2.1),

c. characteristics and trends of processes and products including opportunities for preventive action, and

d. suppliers.

8.5 Improvement:

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

8.5.2 Corrective Action: The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a. reviewing nonconformities (including customer complaints),

b. determining the causes of nonconformities,

c. evaluating the need for action to ensure that nonconformities do not recur,

d. determining and implementing action needed,

e. records of the results of action taken (see 4.2.4),

f. reviewing corrective action taken,

g. flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and

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

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

A documented procedure shall be established to define requirements for

a. determining potential nonconformities and their causes,
b. evaluating the need for action to prevent occurrence of nonconformities,
c. determining and implementing action needed,
d. records of results of action taken (see 4.2.4), and
e. reviewing preventive action taken.

ANNEX A
BIBLIOGRAPHY

AS/EN/SJAC 9102	*Aerospace First Article Inspection Requirement*
ISO 9000:2000	*Quality management systems – Fundamentals and vocabulary*
ISO 9001:2000	*Quality management systems – Requirements*
ISO 9004:2000	*Quality management systems – Guidelines for performance improvements*
ISO 10007:1995	*Quality management — Guidelines for configuration management*
ISO 10011-1:1990	*Guidelines for auditing quality systems — Part 1: Auditing*[2]
ISO 10011-2:1991	*Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*[2]
ISO 10011-3:1991	*Guidelines for auditing quality systems — Part 3: Management of audit programmes*[2]
ISO 10012-1:1992	*Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*
ISO 10012-2:1997	*Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes*

[2] To be revised as ISO 19011, Guidelines on quality and/or environmental management systems auditing.

SECTION 2 - QUALITY SYSTEMS MODEL FOR QUALITY ASSURANCE IN DESIGN, DEVELOPMENT, PRODUCTION, INSTALLATION AND SERVICING
BASED ON ISO 9001:1994

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1. SCOPE:

This standard includes ISO 9001:1994[1] quality system requirements and specifies additional requirements for the quality system of the aerospace industry.

For those not involved in design activities (ref. ISO 9002:1994), 4.4 is not applicable.

It is emphasized that the quality system requirements specified in this standard are complementary (not alternative) to the contractual and applicable law and regulatory requirements.

2. NORMATIVE REFERENCE:

The following standard contains provisions which, through reference in this text, constitute provisions of this document. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this document are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC (***International Electrotechnical Commission***) and ISO (***International Organization for Standardization***) maintain registers of currently valid International Standards.

ISO 8402:1994 Quality management and quality assurance - Vocabulary

NOTE 1 For informative references, see Annex A.

Notes are for guidance only and are not a part of the requirements of the document.

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[1] With the permission of the International Organization for Standardization (ISO). The complete standard may be obtained from any ISO member or from the ISO Central Secretariat, Case Postale 56, 1211 Geneva 20, SWITZERLAND. Copyright remains with ISO.

3. DEFINITIONS:

For the purposes of this document, the definitions are given in the International Standard ISO 8402 and the following definitions apply.

3.1 Product:

Result of activities or processes.

NOTES:

2 A product may include service, hardware, processed materials, software or a combination thereof.

3 A product can be tangible (e.g., assemblies or processed materials) or intangible (e.g., knowledge or concepts), or a combination thereof.

4 For the purposes of this document, the term " product " applies to the intended product offering only and not to unintended " by-products " affecting the environment. This differs from the definition given in ISO 8402.

3.2 Tender:

Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

3.3 Contract:

Agreed requirements between a supplier and customer transmitted by any means.

3.4 Key Characteristics:

The features of a material or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

4. QUALITY SYSTEM REQUIREMENTS:

NOTE This clause reproduces clause 4 of ISO 9001:1994. Additional International Aerospace Industry requirements are shown in italics and bold.

4.1 Management Responsibility:

4.1.1 Quality Policy: The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers.

The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.1.2 Organization:

4.1.2.1 Responsibility and Authority: The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

a. initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;

b. identify and record any problems relating to the product, process and quality system;

c. initiate, recommend or provide solutions through designated channels;

d. verify the implementation of solutions;

e. control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Resources: The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

4.1.2.3 Management Representative: The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for:

a. ensuring that a quality system is established, implemented and maintained in accordance with this document, and

b. reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

The Management representative shall have the necessary authority and organizational freedom to resolve matters pertaining to quality.

4.1.2.4 Process Performer: Suppliers having a quality assurance activity performed by an individual process performer (e.g., operator, buyer, planner) shall have procedures that define the specific tasks and responsibilities that are authorized and the corresponding requirements and training necessary to perform those tasks.

4.1.3 Management Review: The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this document and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

4.2 Quality System:

4.2.1 General: The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this document. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

Other Quality System requirements imposed by the applicable Regulatory Authorities shall be included or referenced in the Quality System documentation.

4.2.2 Quality System Procedures: The supplier shall:

a. prepare documented procedures consistent with the requirements of this document and the supplier's stated quality policy,

b. effectively implement the quality system and its documented procedures,

c. ensure that quality system procedures are readily accessible to personnel who are responsible for performing work in conformance to requirements, and to customer and/or regulatory authorities representatives.

For the purposes of this document, the range and detail of the procedures that form part of the quality 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 activity.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 Quality Planning: The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

a. the preparation of quality plans;

b. the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality; ***the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics;***

c. ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation;

d. the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

e. the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;

f. the identification of suitable verification at appropriate stages in the realization of product; ***the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization;***

g. the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

h. the identification and preparation of quality records (see 4.16);

i. the identification and selection of subcontractors;

j. the establishment of appropriate process controls and development of control plans where key characteristics have been identified;

k. ***the identification of material, processes and services to support operation and maintenance of the product.***

NOTE 8 The quality plans referred to [see 4.2.3a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

4.2.4 Configuration Management: The supplier shall establish, document and maintain a configuration management process appropriate to the product.

NOTE Guidance on configuration management is given in ISO 10007.

4.3 Contract Review:

4.3.1 General: The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

The supplier shall also establish and maintain documented procedures for tender review and for the coordination of these activities.

4.3.2 Review: Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that:

a. the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;

b. any differences between the contract or order requirements and those in the tender are resolved;

c. the supplier has the capability to meet the contract or order requirements;

d. risk associated with new technology and/or short delivery time scale have been evaluated.

4.3.3 Amendment to a Contract: The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

Contract review requirements shall also apply to contract amendment.

4.3.4 Records: Records of contract reviews shall be maintained (see 4.16).

NOTE 9 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

4.4 Design Control:

4.4.1 General: The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

The responsibilities and authorities for the approval of the design data shall be defined.

When the supplier subcontracts design or development activities, the supplier shall control the subcontracted activity consistent with the requirements of clause 4.6.

4.4.2 Design and Development Planning: The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated, as the design evolves.

4.4.2.1 Design and Development Management Planning: ***The supplier shall plan the different phases used to carry out the design and development, in respect of the organization, task sequence, mandatory steps, significant stages and method of configuration control.***

The supplier shall give consideration to the following activities as appropriate:

- ***structure the design effort into significant elements according to the complexity,***

- ***for each element analyze the tasks and the necessary resources for its design and development. (This analysis shall consider an identified responsible person, design content, planning constraints, and performance conditions).***

4.4.2.2 Reliability, Maintainability, Safety: ***The different design and development tasks to be carried out shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.***

4.4.3 Organizational and Technical Interfaces: Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

4.4.4 Design Input: Design input requirements relating to the product including applicable statutory and regulatory requirements shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

Design input shall take into consideration the results of any contract review activities.

The input data to the design shall be defined and documented in terms of functional requirements.

In the case of a product requiring design and development planning the supplier shall establish the input data specific to each element and shall review to ensure consistency with requirements.

4.4.5 Design Output: Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.

Design output shall:

a. meet the design input requirements;

b. contain or make reference to acceptance criteria;

c. identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance and disposal requirements).

Design output documents shall be reviewed before release.

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the supplier, for example:

- drawings, part lists, specifications;

- a listing of those drawings, part lists, specifications, necessary to define the configuration and the design features of the product;

- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

4.4.6 Design Review: At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16).

Consideration shall be given to:

- ***the validity of design in relation to the objectives of the design stage;***
- ***actions which need to be taken in the event of any identified deviation;***
- ***decision necessary for progression to the next stage.***

4.4.7 Design Verification: At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16).

NOTE 10 In addition to conducting design reviews (see 4.4.6), design verification may include activities such as:

- performing alternative calculations,
- comparing the new design with a similar proven design, if available,
- undertaking tests and demonstrations, and
- reviewing the design stage documents before release.

4.4.8 Design Validation: Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.

NOTES:

11 Design validation follows successful design verification (see 4.4.7).

12 Validation is normally performed under defined operating conditions.

13 Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.

14 Multiple validations may be performed if there are different intended uses.

4.4.8.1 Documentation of Design Verification and Validation: ***At the completion of development, the supplier shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions and the product will function correctly.***

4.4.8.2 Design Verification and Validation Testing**: **Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

- ***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;***
- ***test procedures describe the method of operation, the performance of the test, and the recording of the results***;
- ***the correct configuration standard of the product is submitted for the test;***
- ***the requirements of the test plan and the test procedures are observed;***
- ***the acceptance criteria are met.***

4.4.9 Design Changes: All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation.

Design change approval

The supplier's design control shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.

4.5 Document and Data Control:

4.5.1 General: The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this document including, to the extent applicable, documents of external origin such as standards and customer drawings.

NOTE 15 Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.5.2 Document and Data Approval and Issue: The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a. the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b. invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

c. any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

When customer furnished digital data is used for design, production and/or inspection, the supplier shall establish system controls in accordance with customer requirements.

4.5.3 Document and Data Changes: Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.

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

Document change incorporation: the supplier shall establish a process to ensure the timely review, distribution, implementation and maintenance of all authorized and released drawings, standards, specifications, planning, and changes. The supplier shall maintain a record of change incorporation and, when required, shall coordinate these incorporations with the customer and/or regulatory authority.

4.6 Purchasing:

4.6.1 General: The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements.

The supplier shall be responsible for the quality of all products purchased from subcontractors, including customer-designated sources.

4.6.2 Evaluation of Subcontractors: The supplier shall:

a. evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;

b. define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;

c. establish and maintain quality records of acceptable subcontractors (see 4.16);

d. ensure where required that both the supplier and all subcontractors use customer-approved special process sources;

e. ensure that the organization having responsibility for approving subcontractor quality systems has the authority to disapprove the use of sources;

f. periodically review subcontractor performance; records of these reviews shall be maintained and used as a basis for establishing the level of supplier controls to be implemented;

g. maintain procedures that define the necessary actions to take when dealing with subcontractors which do not meet requirements.

A list of approved subcontractors shall be maintained and shall specify the scope of approval.

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

a. the type, class, grade or other precise identification;

b. the title or other positive identification, and applicable issues 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;

c. the title, number and issue of the quality system standard to be applied;

d. design, test, examination, inspection and customer acceptance requirements and any related instructions and requirements;

e. right of access by the purchaser, their customer and regulatory authorities to all facilities involved in the order and all applicable quality records;

4.6.3 (Continued):

f. requirements for test specimens (production method, number, storage conditions etc.) for design approval, inspection, investigation or auditing;

g. requirements relative to the notification of anomalies, changes in definition and the approval of their processing;

h. requirements to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

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

4.6.4 Verification of Purchased Product: ***The supplier shall implement procedures to verify purchased products. These may include:***

- obtaining objective evidence of the quality of the product from subcontractors (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control);

- inspection and audit at source;

- review of the required documentation;

- inspection of products at delivery;

- delegation of verification to the subcontractor, or subcontractor certification.

When delegation is used the supplier shall define the requirements for delegation and maintain a list of delegations.

4.6.4.1 Supplier Verification at Subcontractor's Premises: Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.

4.6.4.2 Customer Verification of Subcontracted Product: Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.

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.

4.7 Control of Customer-Supplied Product:

The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16).

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

4.8 Product Identification and Traceability:

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.

Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

According to the level of traceability required by contract, regulatory, or other established requirement, the supplier's system shall provide for:

- ***identification to be maintained throughout the product life;***
- ***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;***
- ***for an assembly, the identity of its components and those of the next higher assembly to be traced;***
- ***for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.***

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

4.9 Process Control:

4.9.1 General: The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

a. documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

b. use of suitable production, installation and servicing equipment, and a suitable working environment ***(e.g., temperature, humidity, lighting and cleanness, etc.);***

c. compliance with reference standards/codes, quality plans and/or documented procedures;

d. monitoring and control of suitable process parameters and product characteristics; ***monitoring and control of key characteristics where required by purchase order/contract;***

e. the approval of processes and equipment, as appropriate;

f. criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations);

g. suitable maintenance of equipment to ensure continuing process capability;

h. accountability for all product during manufacture (e.g., parts quantities, split orders, nonconformities);

i. evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized;

j. provision for the prevention, detection, and removal of foreign objects;

k. utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality.

4.9.1.1 Production Documentation: ***Production operations shall be carried out in accordance with approved data.***

This data shall contain as necessary:

- ***drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents;***
- ***a list of specific or non-specific tools and numerical control (NC) machine programs;***
- ***documents associated with specific tools enabling the tools to be designed, produced, validated, controlled, used and maintained.***

4.9.1.2 Control of Production Process Changes: ***Persons required to approve changes to production processes shall be identified and authorized.***

The supplier shall identify those changes which require customer acceptance in accordance with contractual requirements prior to making any change.

Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.

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

4.9.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs: ***Production equipment, tools and programs shall be validated prior to use, maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.***

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

4.9.1.4 Control of Work Occasionally Performed Outside the Supplier's Facilities: ***When planning to carry-out work at a location other than its normal facilities, the supplier shall define the procedure to validate the location and to control the work.***

4.9.2 Special Processes: Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified.

NOTE 16 Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).

When production operations call for special processes, the following requirements shall apply:

- ***the special processes to be implemented shall be identified and qualified prior to use;***
- ***the supplier shall control applicable aspects of special processes, as defined by the process specifications, this includes special process changes;***
- ***the supplier shall define the significant operations and parameters in the process to be controlled during production.***

4.10 Inspection and Testing:

4.10.1 General: The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

These procedures shall specify the resources and methods to be implemented, and methods of recording the results.

These procedures shall include:

- ***identification of authorized personnel;***
- ***limits of authorization;***
- ***training and qualification requirements.***

4.10.1 (Continued):

Inspection documentation shall be maintained and controlled by the supplier. This may be part of the manufacturing documentation, but shall include:

- ***criteria for acceptance and rejection;***
- ***where in the sequence inspection and testing operations are performed;***
- ***documents recording inspection results;***
- ***identification of production inspection instruments;***
- ***documents associated with specific inspection instruments enabling them to be designed, produced, validated, controlled, used and maintained.***

When the supplier subcontracts inspection or test activities, the supplier shall control the subcontracted activity consistent with the requirements of clause 4.6.

4.10.2 Receiving Inspection and Testing:

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) 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.

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

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

4.10.2.4 When certification test reports are utilized to accept material, the supplier shall assure that data in said reports are acceptable per applicable specifications. The supplier shall periodically validate test reports.

4.10.3 In-Process Inspection and Testing: The supplier shall:

a. inspect and test the product as required by the quality plan and/or documented procedures;

b. 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 (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3a).

4.10.4 Final Inspection and Testing: The supplier 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 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 authorized.

4.10.5 Inspection and Test Records: The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

Test records shall show actual test results data when required by specification or acceptance test plan.

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

4.10.6 First Article Inspection: ***The supplier's system shall provide a process, as appropriate, for the inspection, verification, and documentation of the first production article.***

First Article Inspection documentation shall be retained (see 4.16) and shall include a list of the characteristics required by the design data and any required tolerances, the actual results, and when testing is required, the results of the tests.

The First Article Inspection shall be updated to include production process changes or configuration changes.

4.11 Control of Inspection, Measuring and Test Equipment:

4.11.1 General: The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier 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.

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 supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

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.

NOTE 17 For the purposes of this document the term "measuring equipment" includes measurement devices.

NOTE Inspection, measuring and test equipment includes all types of devices used by any supplier or subcontractor personnel to validate materials, products, processes or other inspection, measuring and test equipment. This includes test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned equipment used for product acceptance.

Responsibilities shall be defined regarding the control of inspection, measuring and test equipment, including those used by operators as well as, where appropriate, test devices and tools supplied by the customer.

4.11.2 Control Procedure: The supplier shall:

a. 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;

b. 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;

The supplier shall maintain a list of this equipment, including where appropriate, test devices and tools supplied by the customer;

c. 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 and the action to be taken when results are unsatisfactory;

d. identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

e. maintain calibration records for inspection, measuring and test equipment (see 4.16);

f. assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;

When the assessment indicates that the product may be nonconforming, disposition the nonconformance.

g. ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

h. ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;

i. safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting;

j. define the method for recall of measuring devices that require calibration.

NOTE 18 The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

4.12 Inspection and Test Status:

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed.

The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.

4.12.1 Authorized Personnel: ***Records shall identify personnel authorized to verify, certify and release products.***

4.12.2 Acceptance Authority Media: ***When acceptance authority media are used (e.g., stamps, electronic signatures or passwords), the supplier shall establish and document controls for the media.***

4.13 Control of Nonconforming Product:

4.13.1 General: The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

The procedures established by the supplier shall also take into account process nonconformity that may result in product nonconformity.

NOTE Parties requiring notification of nonconforming product may include subcontractors, internal organizations, customers, distributors and regulatory authorities.

The term "nonconforming product includes nonconforming product returned from a customer.

4.13.2 Review and Disposition of Nonconforming Product: The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a. reworked to meet the specified requirements,
b. accepted with or without repair by concession,
c. regraded for alternative applications, or
d. rejected or scrapped.

4.13.2 (Continued):

Where required by the contract, the proposed use or repair of product [see 4.13.2b)] which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

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

The supplier's documented procedures shall define the process for approving personnel making material review decisions.

4.13.2.1 Material Review Authority**: **Notwithstanding the requirements of 4.13.2, the supplier shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if (1) the product is produced to customer design, or (2) the nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, supplier-designed product which is controlled via a customer specification may be dispositioned by the supplier as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

4.13.2.2 Regrading Material**: **Product dispositioned for regrade requires a change in product identification to preclude the product's original use. Adequate test reports and certifications shall reflect the regrading.

4.13.2.3 Scrap Material**: **Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

4.13.2.4 Notification**: **The supplier's system shall provide for timely reporting of nonconformities that may affect product already delivered including any continuing airworthiness actions. Notification shall include a clear description of the nonconformance, which includes as necessary parts affected, customer and/or supplier part numbers, quantity, and date(s) delivered.

4.14 Corrective and Preventive Action:

4.14.1 General: The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.2 Corrective Action: The procedures for corrective action shall include:

a. the effective handling of customer complaints and reports of product nonconformities;

b. investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see 4.16);

c. determination of the corrective action needed to eliminate the cause of nonconformities;

d. application of controls to ensure that corrective action is taken and that it is effective;

e. flow down of the corrective action requirement to a subcontractor, when it is determined that the subcontractor is responsible for the root cause;

f. specific actions where timely and/or effective corrective actions are not achieved.

4.14.3 Preventive Action: The procedures for preventive action shall include:

a. the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities;

b. determination of the steps needed to deal with any problems requiring preventive action;

c. initiation of preventive action and application of controls to ensure that it is effective;

d. ensuring that relevant information on actions taken is submitted for management review (see 4.1.3).

4.15 Handling, Storage, Packaging, Preservation and Delivery:

4.15.1 General: The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

These procedures shall also cover the specific requirements for:

- cleaning;
- prevention, detection and removal of foreign objects;
- special handling for sensitive products;
- marking and labeling including safety warnings;
- shelf life control and stock rotation;
- hazardous materials

where applicable in accordance with product specifications and/or applicable regulations.

4.15.2 Handling: The supplier shall provide methods of handling product that prevent damage or deterioration.

4.15.3 Storage: The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

4.15.4 Packaging: The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation: The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

4.15.6 Delivery: The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

The supplier shall ensure that the accompanying documents for the product are present at delivery as specified in the contract/order and are protected against loss and deterioration.

4.16 Control of Quality Records:

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All 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.

Records shall be available for review by regulatory authorities as required.

NOTE 19 Records may be in the form of any type of media, such as hard copy or electronic media.

4.17 Internal Quality Audits:

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).

The supplier shall conduct internal quality audits that assess compliance to their quality system and the requirements of this document. A flow down of the requirements from this document through the supplier's quality manual to the working-level procedures must be shown. Detailed tools and techniques shall be developed such as checksheets, process flowcharts, or any similar method to support audit of the procedural requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall supplier performance.

The supplier's personnel carrying out these audits shall have received appropriate training.

NOTE 20 The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).

NOTE 21 Guidance on quality system audits is given in ISO 10011.

4.18 Training:

The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality.

Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16).

Training to achieve and maintain an awareness and understanding of relevant procedures and instructions, shall be provided.

4.19 Servicing:

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.

These procedures shall contain:

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

4.20 Statistical Techniques:

4.20.1 Identification of Need: The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

4.20.2 Procedures: The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

According to the nature of the product and depending on the criticality and the specified requirements, these statistical techniques may be used to support:

- ***design verification (e.g., reliability, maintainability, safety);***
- ***process control:***
  - ***selection and inspection of key characteristics;***
  - ***process capability measurements;***
  - ***statistical process control;***
  - ***design of experiment;***
- ***inspection: matching sampling rate to the criticality of the product and to the process capability;***
- ***quality management: use of statistical techniques to determine required improvement activities;***
- ***failure mode and effect analysis.***

4.20.2 (Continued):

When the supplier uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of known defectives in the lot. When required, the plan shall be submitted for customer approval.

ANNEX A
BIBLIOGRAPHY

ISO 8402:1994	*Quality management and quality assurance - Vocabulary*
ISO 9001:1994	*Quality systems - Model for quality assurance in design, development, production, installation and servicing*
ISO 9002:1994	*Quality systems - Model for quality assurance in production, installatioin and servicing*
ISO 10007:1995	*Quality management - Guidelines for configuration management*
ISO 10011-1:1990	*Guidelines for auditing quality systems - Part 1: Auditing*
ISO 10011-2:1991	*Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors*
ISO 10011-3:1991	*Guidelines for auditing quality systems - Part 3: Management of audit programmes*
ISO 10012-1:1992	*Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment*
ISO 10012-2:1997	*Quality assurance for measuring equipment - Part 2: Guidelines for control of measurement processes*
ISO 10013:1995	*Guidelines for developing quality manuals*