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AEROSPACE STANDARD

SAE AS9100®
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Quality Systems
- Aerospace -
Model for Quality Assurance
in Design, Development, Production, Installation and Servicing

FOREWORD

In December 1998, the Aerospace Industry had established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream.

This organization, with representation from Aerospace companies in Americas, Asia and Europe and sponsored by SAE, SJAC, and AECMA has agreed to take responsibility for the technical contents of this standard.

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1. SCOPE:

This standard includes ASQ 9001:1994 quality system requirements and specifies additional requirements for the quality system of the aerospace industry.

For those not involved in design activities (Ref. ASQ 9002), 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 REFERENCES:

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.

ANSI/ISO/ASQC Q9001:1994; Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing (a word-for-word equivalent to ISO9001) has been reproduced in this document with the permission of the American Society for Quality. The complete standard can be obtained from the American Society for Quality, 611 E. Wisconsin Ave., Milwaukee, WI 53202. Copyright remains with the American Society for Quality.

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

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

NOTE 1: For informative references, see Annex A.

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[1] clause 4 of ASQ 9001:1994. Additional International Aerospace Industry requirements are shown in italics and bold.***

1. With the permission of the American Society for Qualtiy (ASQ). The complete standard may be obtained from ASQ, 611 E. Wisconsin Ave., Milwaukee, WI 53202.

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 paragraph 4.4.

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 e.g.:

- ***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 subtier 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 section 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.