

Submitted for recognition as an American National Standard

Editorial Revision Only

Aerospace Basic Quality System Standard

NOTICE

This revision contains only editorial changes to the Reference Section.

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1. SCOPE:

To assure customer satisfaction, aerospace industry manufacturers must produce world class quality products at the lowest possible cost. This document standardizes, to the greatest extent possible, the quality system requirements of the aerospace industry. Standardization of compliance requirements results in cost savings due to the elimination or reduction of unique requirements developed for each different customer.

1.1 Quality Philosophy:

Eliminating the causes of defects is paramount to continuous quality improvement. Process activities should, to the greatest extent practicable, be directed toward defect prevention methods, such as statistical process control and variability reduction, error proofing, and visual controls, rather than defect detection.

Responsibility for quality ultimately rests with those organizations having ownership of the processes affecting product quality.

2. REFERENCES:

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.

Q9001 (ISO9001) Section 4 requirements are reproduced in Section 4 of this document. Additional industry requirements and notes in Section 4 are shown in bold.

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

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

3. DEFINITIONS:

For the purposes of this document, the definitions given in International Standard ISO 8402, Quality Management and Quality Assurance - Vocabulary, and the following definitions apply:

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

REGRADE: A disposition of a nonconformity that (1) determines that the product is not acceptable for its original intended design, and (2) directs the product to be redesignated or modified for an alternate use.

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4. QUALITY SYSTEM REQUIREMENTS:

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

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4.1.2.4 Suppliers having a quality assurance activity performed by an individual process owner (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: Guidance on quality manuals is given in ISO 90013.

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 available to personnel who are responsible for compliance to requirements, and to customer and/or regulatory agency 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: Documented procedures may make reference to work instructions that define how an activity is performed.

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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;
(1) the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics;
- c. ensuring the compatibility of 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;
(1) 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 capable of meeting quality requirements and the appropriate flowdown of requirements (see 4.6.5);**
- j. **the establishment of appropriate process controls and development of control plans if key characteristics have been identified by the customer.**

NOTE: 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.

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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.

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.

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.

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

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

4.4 Design Control:

NOTE: Compliance with Section 4.4 is only required by suppliers with design responsibility for the product being produced.

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.

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.

4.4.3 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.

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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.

4.4.5 Design Output: Design output shall be documented and expressed in terms that can be verified against design-input requirements and validated (see 4.4.8).

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.

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).

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

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

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

NOTES:

1. Design validation follows successful design verification (see 4.4.7).
2. Validation is normally performed under defined operating conditions.
3. Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.
4. Multiple validations may be performed if there are different intended uses.

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

4.4.9.1 Design Change Approval: The supplier's design control system shall provide for customer and/or regulatory agency approval of changes, when required.

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: 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.

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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.

4.5.3.1 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 effectivity and, when required, shall coordinate these effectivities with the customer.

4.6 Purchasing:

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

NOTE: This requirement also applies to product obtained from 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;

NOTE: Definition of the extent of control should include a system for disapproval, if necessary.

- c. establish and maintain quality records of acceptable subcontractors (see 4.16);
- d. **ensure that both the supplier and all subcontractors use customer-approved special process sources, as required by contract.**

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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.

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

4.6.4 Verification of Purchased Product:

NOTE: Verification methods for purchased product may include receiving/source verification, delegation of verification to the subcontractor, or subcontractor certification.

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.

4.6.4.3 Right of Entry: The supplier shall include provisions in subcontracts to allow the supplier, customer, and regulatory agencies right of entry to any place necessary to determine and verify the quality of contracted work, records and material.

4.6.4.4 Delegation of Supplier Verification to Subcontractors: Where the supplier proposes to delegate product verification to a subcontractor, the supplier shall define the requirements for the delegation and maintain a list of the delegations.

4.6.5 Requirements Flowdown: The supplier shall flow down quality system requirements to subcontractors to the extent necessary to ensure that characteristics not verifiable upon receipt are adequately controlled by the subcontractor. Key characteristics requirements shall be flowed down if the supplier subcontracts the key characteristics process.

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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).

4.9 Process Control:

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;
- c. compliance with reference standards/codes, quality plans and/or documented procedures;
- d. monitoring and control of suitable process parameters and product characteristics;
(1) monitoring and control of key characteristics when 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., part quantities, split orders, nonconformities);**

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4.9 (Continued):

- i. evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized;**
- j. provisions for the prevention, detection, and removal of foreign objects.**

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: 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).

4.9.1 Process Specification Requirements: When special processes requiring customer approval are required by drawing, specification, or purchase order, the supplier shall obtain qualification prior to processing or subcontract the process to a customer approved source.

4.9.2 Tooling: The supplier's system shall maintain and control production tooling to ensure that the product meets design requirements.

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.

4.10.1.1 Subcontracting Inspection Activities: When the supplier proposes to subcontract inspection 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.

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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 used as a means of product acceptance, procedures shall document the types and frequencies of analyses to validate certifications.

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).

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

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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: For the purposes of this document, the term "measuring equipment" includes measurement devices.

4.11.1.1 Definition: Inspection, measuring and test equipment includes all types of devices used by any supplier or subcontractor personnel to verify materials, products, processes, or other inspection, measuring and test equipment. This includes tooling used as media of inspection, test hardware, test software, automated test equipment (ATE), and plotters used to produce inspection media. Also included is personally owned equipment used for product or process acceptance.

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;
- 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;

(1) the process shall consider the recall of inspection equipment, as appropriate.

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4.11.2 (Continued):

- 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;
- 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.

NOTE: 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 Acceptance Authority Media: When acceptance authority media are used (e.g., stamps, electronic passwords), the supplier's system 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.