SAE Aerospace
An SAE International Group

AEROSPACE STANDARD

SAE AS9120

Issued 2002-10

Quality Management Systems - Aerospace Requirements for Stockist Distributors

FOREWORD

To assure customer satisfaction, aerospace industry organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory agency 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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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 the 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.

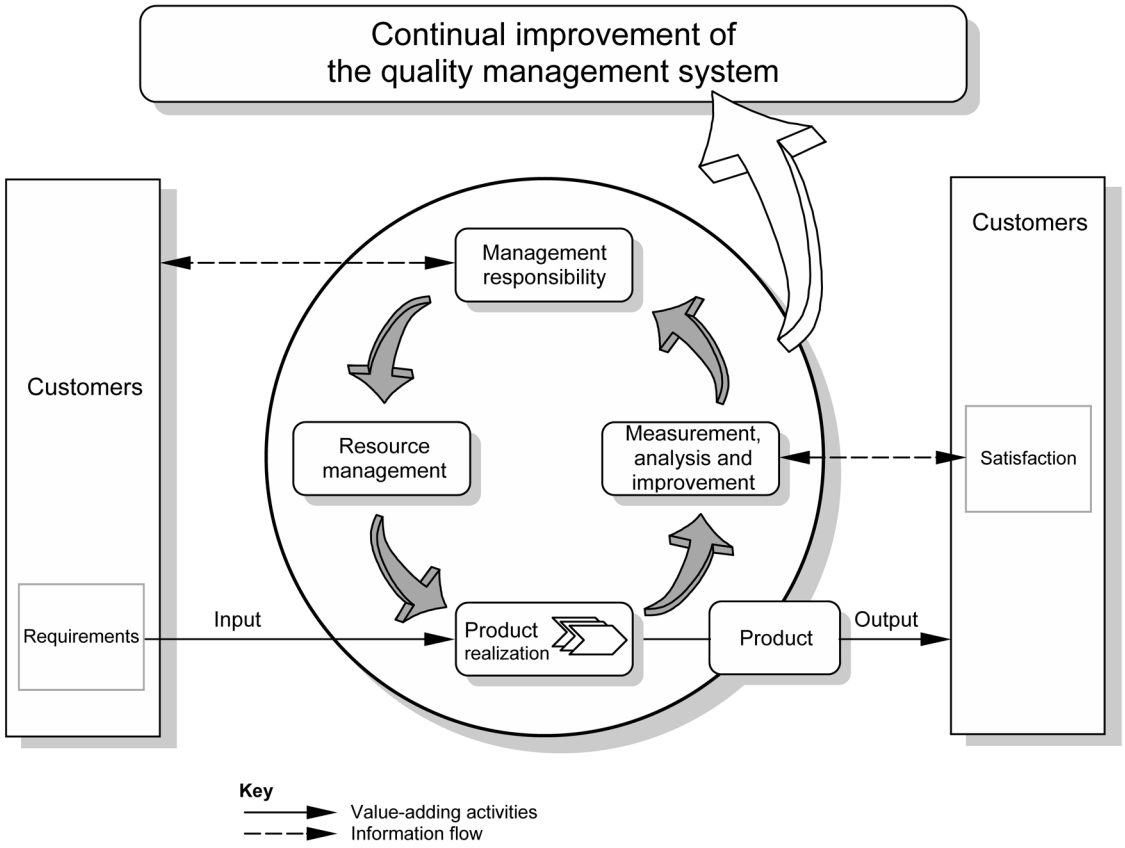

FIGURE 1 - Model of a Process-Based Quality Management System

SAE AS9120

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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 applicable to stockist distributors. 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.

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.

1.2 (Continued):

This standard is for use by organizations that procure parts, materials and assemblies and sells these products to a customer in the aerospace industry. This includes organizations that procure products and split them into smaller quantities. This standard is not intended for organizations that rework or repair products. Organizations that perform work that affect or could affect product characteristics or conformity shall use AS/EN/JIS Q 9100 or another quality management system standard.

The following ISO 9001:2000 clauses are excluded in their entirety for purposes of the AS/EN/SJAC 9120 requirements for stockist distributors: 7.1, 7.3, 7.5.2.

2. NORMATIVE REFERENCE:

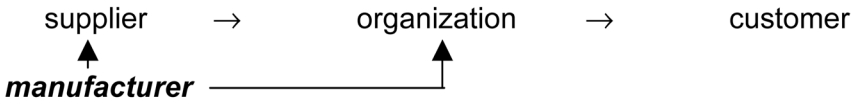
The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International 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:



For the purpose of this document, the term manufacturer is intentionally used to clearly delineate the product creator.

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”.

3. (Continued):

Airworthiness Certificate: A document issued by the cognizant civil aviation authority (e.g., JAA Form 1, FAA Form 8130-3) that certifies that the part has been manufactured, overhauled, or repaired in accordance with, and conforms to, the applicable airworthiness regulations.

Manufacturer's Certificate/Test Report: A document issued by the product manufacturer that certifies product conformance to process, design, and/or specification requirements.

Splitting:

- ***batch splitting - the separation of entities, such as sheets, bars, components, parts, fasteners, and containers belonging to the same production batch.***

- ***product splitting - physically dividing a solid entity such as bar, sheet, plate (metallic or non-metallic material) or partial decanting of a gaseous or liquid entity, where the physical and metallurgical properties or chemical characteristics are not altered.***

Splitting shall not affect the conformance of the product as defined by the original product specification.

Stockist Distributors: Organization carrying out the purchase, storage, splitting and sale of products without affecting product conformance. The term organization in the context of this standard means a stockist distributor.

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,

4.1 (Continued):

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.

4.2.1 (Continued):

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 maintain appropriate documentation to verify the status of the product (e.g., manufacturer's data, standards, airworthiness data).

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.

These records shall include where applicable:

a. manufacturer, distributor, repair station, test and inspection reports;
b. original certificates of conformity (manufacturer, sub-tier distributor), copies of airworthiness certificates;
c. non-conformance, concession and corrective action records;
d. lot traceability records;
e. environmental or shelf life condition records.

Where records are stored in an electronic form, the integrity of the system and the back-up procedures shall be appropriately validated. These records, without possibility of change by software, shall be traceable to the original documentation.

Records of product origin, conformity, and shipment shall be maintained for a minimum of seven years, or as required by contract.

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

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.

NOTE: Reference to clause 7.1 a. is not required.

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 and maintain product conformity.

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, and

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:

NOTE: This clause not required for conformance to this standard.

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.

7.2.2 (Continued):

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:

NOTE: This clause not required for conformance to this standard.

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 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 sources of supply that includes the scope of the approval;

b. periodically review source of supply 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. prevent the purchase of counterfeit/suspect unapproved products.

The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated 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/product description or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data (e.g., revision level),

e. requirements relative to supplier notification to organization of nonconforming product,

f. requirements for the supplier to notify the organization of changes in product definition,

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

h. requirements for a certificate of conformity, test reports, and/or airworthiness approval from the approved manufacturer or approved repair station.

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 and verifying the authenticity of the accompanying documentation (e.g., certificate of conformity from the manufacturer, airworthiness certificate, test reports, statistical records, process control),

b. review of the required documentation, and

c. inspection of products upon receipt.

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.

7.4.3 (Continued):

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

7.5.2 Validation of Processes for Production and Service Provision:

NOTE: This clause not required for conformance to this standard.

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

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).

The organization shall establish and maintain documented procedures for product identification and traceability by suitable means (e.g., labels, bar codes or other) from receipt; during splitting, storage packaging, and preservation operations; and until delivery (including subcontracted handling or packing operations).

7.5.3 (Continued):

The organization's processes shall provide for:

a. maintaining the manufacturer's identification and batch/lot traceability;

b. the ability to identify and trace products manufactured from the same batch of raw material or from the same manufacturing batch, as well as the ability to trace the product to the ultimate destination (delivery, scrap);

c. maintaining the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

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.

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, and
g. environmental controls (e.g., temperature, humidity).

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.

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.

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.

NOTE: According to the nature of the product and the activities performed statistical techniques may be used for:

- ***Inspection: matching sampling rate to the criticality of the product;***
- ***Quality management: use of statistical techniques to determine required improvement activities.***

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.

NOTE: Reference to clause 7.1 is not required.

An audit program 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.

8.2.2 (Continued):

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).

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 inspections are performed to verify product status and the organization uses sampling inspection as a means of verification, 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.

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.

NOTE: References to clause 7.1 are not required.

8.2.4.1 Inspection Documentation: Measurement requirements for product or service acceptance shall be documented and include:

a. criteria for acceptance and/or rejection,
b. a record of the measurement results, and
c. 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.

8.2.5 Evidence of Conformance - Certificate of Conformity: When required, the organization shall provide the customer with evidence of the product's conformity to its technical specifications. This may include the manufacturer's conformance documents, the original airworthiness certificate, test analysis, and/or test reports.

When splitting product, copies of original documents shall be annotated with the following information: amount delivered relative to amount received, purchase order number, customer's name, and supplier's name.

Where there is a formal agreement with the customer, the organization may deliver a certificate of conformity created by the organization that references the original manufacturer's conformance documents that are retained and traceable by the organization.

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 and suspected unapproved parts.

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.

Dispositions shall be limited to:

- scrap;
- rejection for return to the supplier;
- rejection for revalidation by the manufacturer;
- submittal to design authority and customer for "USE AS IS" disposition.

NOTE: The stockist distributor has no authority to rework or repair product.

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

The organization shall ensure, with the manufacturer where necessary, that similar supplies are not similarly affected and shall inform the customer of any nonconformities affecting product already delivered.

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 and/or the manufacturer, when it is determined that the supplier and/or the manufacturer 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),
e. reviewing preventive action taken***, and***
f. the withdrawal of product(s) from stock that are suspected of a noncompliance (or returned by a customer), including notification of all customers of the action(s) taken who have purchased the product from the same lot or batch.

PREPARED UNDER THE JURISDICTION OF
SAE COMMITTEE G-14, AMERICAS AEROSPACE QUALITY GROUP

APPENDIX A
BIBLIOGRAPHY

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