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(R) Inspection and Test Quality Systems
Requirements for Aviation, Space, and Defense Organizations

RATIONALE

This standard has been revised using AS9100:2009 as the baseline document. AS9100:2009 requirements applicable to noncomplex products and manufacturing processes have been incorporated into this standard and modified, as necessary, to reflect the intent of this standard. The standard's clauses have been renumbered accordingly.

FOREWORD

To assure customer satisfaction, aviation, space, and defense organizations must produce, and continually improve safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

This document standardizes, to the greatest extent possible, inspection and test quality system requirements for suppliers that provide noncomplex products. Hereafter, the term "inspection and test quality system" is referred to as "quality system".

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TABLE OF CONTENTS

RATIONALE	1
FOREWORD	1
INSPECTION AND TEST QUALITY SYSTEM - REQUIREMENTS	3
1. SCOPE	3
1.1 General	3
1.2 Application	3
2. REFERENCES	3
3. TERMS AND DEFINITIONS	4
3.1 Critical Items	4
3.2 Key Characteristic	4
3.3 Noncomplex Product	4
4. INSPECTION AND TEST QUALITY SYSTEM	4
4.1 General Requirements	4
4.2 Documentation Requirements	4
4.2.1 Quality Manual	4
4.2.2 Control of Documents	4
4.2.3 Control of Records	5
5. MANAGEMENT RESPONSIBILITY	5
5.1 Management Representative	5
6. RESOURCE MANAGEMENT	5
6.1 Human Resources	5
6.2 Work Environment	5
7. PRODUCT REALIZATION	5
7.1 Planning of Product Realization	5
7.1.1 Configuration Management	6
7.2 Customer-Related Processes	6
7.3 Design and Development	6
7.4 Purchasing	6
7.4.1 Purchasing Process	6
7.4.2 Purchasing Information	6
7.4.3 Verification of Purchased Product	7
7.5 Production	8
7.5.1 Control of Production	8
7.5.1.1 Production Process Verification	8
7.5.1.2 Control of Production Process Changes	8
7.5.2 Identification and Traceability	9
7.5.3 Preservation of Product	9
7.6 Control of Monitoring and Measuring Equipment	9
8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT	10
8.1 Monitoring and Measurement of Product	10
8.2 Control of Nonconforming Product	10
8.3 Corrective Action	11
8.4 Internal Audit	11
9. NOTES	12

INSPECTION AND TEST QUALITY SYSTEM - REQUIREMENTS

1. SCOPE

1.1 General

This standard includes selected quality system requirements from ISO 9001:2008^[1] and AS9100:2009 applicable to noncomplex products and associated manufacturing processes. ISO 9001 text incorporated into this standard appears in standard font; while aviation, space, and defense industry additional requirements, definitions, and notes are presented in bold, italic text.

The requirements of this standard are intended to be applied in whole, without any exclusions. Compliance with all corresponding AS9100 requirements is considered to meet/exceed compliance with the requirements of this standard.

The requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.

The process approach described in ISO 9001 and AS9100 applies to this standard.

1.2 Application

The requirements of this standard are generic and are intended to be applicable to all organizations regardless of type and size.

This standard is intended for use by organizations that produce noncomplex products for use in aviation, space, and defense applications. This standard is not intended to apply to organizations that produce complex product or have design responsibility.

2. REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AS9100:2009	Quality Management Systems - Requirements for Aviation, Space and Defense Organizations
ISO 9000:2005	Quality management systems - Fundamentals and vocabulary
ISO 9001:2008	Quality management systems - Requirements
ISO 9004	Managing for the sustained success of an organization - A quality management approach

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3. TERMS AND DEFINITIONS

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

3.1 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.2 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.3 Noncomplex Product

A hardware item whose conformance to quality characteristics can be determined by simple measurement and test of the end item, without uneconomical disassembly or destructive testing.

4. INSPECTION AND TEST QUALITY SYSTEM

4.1 General Requirements

The organization shall establish, document, implement, and maintain a quality system in accordance with the requirements of this standard.

The quality system shall address customer, statutory, and regulatory requirements.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined.

4.2 Documentation Requirements

4.2.1 Quality Manual

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

- a) the scope of the quality system; and
- b) the documented procedures established for the quality system, or reference to them.

The term “documented procedure” means that the procedure is established, documented, implemented, and maintained.

4.2.2 Control of Documents

Documents required by the quality system shall be controlled.

A documented procedure shall 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 determined by the organization to be necessary for the planning and operation of the quality system 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.

4.2.3 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality system shall be controlled. Examples of records include, but are not limited to, records created by and/or retained by suppliers, and records relating to training, product realization, contract review, product traceability, calibration, internal audit, product measurement, nonconforming material disposition, and corrective action.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records. Records shall remain legible, readily identifiable, and retrievable.

5. MANAGEMENT RESPONSIBILITY

5.1 Management Representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes ensuring that processes needed for the quality system are established, implemented, and maintained.

6. RESOURCE MANAGEMENT

6.1 Human Resources

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills, and experience.

6.2 Work Environment

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

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

7. PRODUCT REALIZATION

7.1 Planning of Product Realization

The organization shall plan and develop the processes needed for product realization.

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

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents, and provide resources specific to the product; and

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

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

7.1.1 Configuration Management

The organization shall establish, implement, and maintain a documented process for controlling changes to the as-defined configuration, including authorization from design authorities and records attesting to as-built configuration.

7.2 Customer-Related Processes

Prior to the organization's commitment to supply a product to the customer, the organization shall review all requirements related to the product, including statutory and regulatory requirements, to ensure that the requirements are adequately defined and understood, and confirm that the organization has the ability to meet the defined requirements.

NOTE: This function is often referred to as "contract review".

7.3 Design and Development

NOTE: This clause does not apply 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 be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

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.

The organization shall:

- a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family); and***
- b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented.***

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 system requirements;

- d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions, and other relevant technical data;**
- e) requirements for test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics;**
- f) requirements for test specimens (e.g., production method, number, storage conditions) for inspection/verification, investigation, or auditing;**
- g) requirements regarding the need for the supplier to:**
 - notify the organization of nonconforming product;**
 - obtain organization approval for nonconforming product disposition;**
 - notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location, and, where required, obtain organization approval; and**
 - flow down to the supply chain the applicable requirements, including customer requirements.**
- h) records retention requirements; and**
- i) right of access by the organization, their customer, and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.**

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.

Based on supplier performance reviews [see 7.4.1(b)], verification activities shall include, as applicable:

- a) obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records);**
- b) review of the required documentation; and**
- c) inspection of products upon receipt.**

Where the certification test reports are utilized to verify purchased product, the organization shall assure that data in the test reports is acceptable per applicable specifications.

For raw material that may be used in “critical item” applications, the organization shall independently validate the accuracy of test reports in accordance with a statistically based sampling plan. Where validation is outsourced, the test facility shall be formally qualified to perform the required product testing.

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

7.5 Production

7.5.1 Control of Production

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;

NOTE: This information can include drawings, parts lists, materials, and process specifications.

- b) the availability of work instructions, as necessary;

NOTE: Work instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and inspection documents.

- c) the availability and use of monitoring and measuring equipment;

- d) **accountability for all product during production (e.g., parts quantities, split orders, nonconforming product);**

- e) **evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;**

- f) **provision for the prevention, detection, and removal of foreign objects; and**

- g) **criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).**

Planning shall consider, as appropriate:

- **establishing, implementing, and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified; and**
- **identifying in-process inspection/verification points.**

7.5.1.1 Production Process Verification

The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, documentation, and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

NOTE: This activity is often referred to as “first article inspection”.

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes shall be identified.

The organization shall control, document, and assess changes affecting production processes, equipment, tools, or software programs to preclude adverse effects to product conformity.

7.5.2 Identification and Traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

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

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

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

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

Traceability requirements shall include, unless otherwise specified by the customer:

- a) identification to be maintained throughout the product life;***
- b) the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);***
- c) for an assembly, the ability to trace its components to the assembly and then to the next higher assembly; and***
- d) for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.***

7.5.3 Preservation of Product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.

Preservation of product shall include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for cleaning, shelf life control, and stock rotation.

7.6 Control of Monitoring and Measuring Equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification, including details of equipment type, unique identification, location, frequency of checks, check method, and acceptance criteria.

The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement, and testing being carried out.

Where necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified, or both, 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) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance, and storage.

The organization shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

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.

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.

8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 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. Evidence of conformity with the acceptance criteria shall be maintained.

Measurement requirements for product acceptance shall be documented and shall include:

- a) criteria for acceptance and/or rejection;***
- b) where in the sequence measurement and testing operations are to be performed;***
- c) required records of the measurement results (at a minimum, indication of acceptance or rejection); and***
- d) any specific measurement instruments required and any specific instructions associated with their use.***

When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.

When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

8.2 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. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

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

Where applicable, 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; and/or
- c) by taking action to preclude its original intended use or application.

The organization's nonconforming product control process shall provide for timely reporting of delivered nonconforming product.

Dispositions of use-as-is or repair shall only be used, after approval by an authorized representative of the organization responsible for design. The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

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

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

8.3 Corrective Action

The organization shall take action to eliminate the causes 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) determining the causes of nonconformities;
- b) evaluating the need for action to ensure that nonconformities do not recur;
- c) determining and implementing action needed;
- d) reviewing the effectiveness of the corrective action taken; ***and***
- e) ***determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action, when required.***

8.4 Internal Audit

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

- a) conforms to planned arrangements and quality system requirements established by the organization, and
- b) is effectively implemented and maintained.

The audit program shall be planned and documented to the extent necessary, 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 and documented.

Auditors shall not audit their own work.

9. NOTES

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