



AEROSPACE STANDARD

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published in all IAQG sectors.

(R) Aerospace Series - Quality Management Systems -
Variation Management of Key Characteristics

RATIONALE

This standard was revised to align with the latest revisions of the International Aerospace Quality Group (IAQG) standards (i.e., 9100, 9110, 9102, 9138, 9145) and to incorporate industry feedback. Other changes made to standard requirements presented herein were editorial in nature for increased clarity, including additional terms and definitions, and references to other relevant external standards.

FOREWORD

To assure customer satisfaction, aviation, space, and defense industry organizations must produce and continually improve safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the 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 external providers throughout the world and at all levels within the supply chain. Industry producers, including external providers, face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The aviation, space, and defense industry established the IAQG for the purpose of achieving significant improvements in quality and safety, and reductions in cost throughout the value stream. This organization includes representation from companies in the Americas, Asia/Pacific, and Europe.

This document standardizes requirements for the variation management of Key Characteristics (KCs). The establishment of common requirements, for use at all levels of the supply chain, 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

0.1 General

This standard establishes variation management requirements for KCs and provides a process to achieve those requirements.

The standard requires a thorough assessment of the applicable manufacturing and maintenance processes with the primary goals being to control and minimize variation in characteristics generated by these processes. Specifically, the standard requires:

- Understanding process elements that affect KCs.
- Disciplined determination of process KCs using appropriate analysis tools for variation control and reduction to satisfy customer requirements.
- Control and capability assessment to ensure variation is well understood.
- Control Plan (CP) that defines specific control of KCs, and manufacturing or maintenance process parameters.

Product acceptance and release are carried out according to customer requirements; this standard cannot be used as the basis for product acceptance and release. This standard does not:

- Require rejection of any part that conforms to engineering specifications.
- Inhibit shipment or use of product during production process capability assessment.

For the purpose of this standard, the variation control process does not apply to lab-scale, pilot, or pre-production processes; however, particular management of some KCs might be required using methods other than those described in this standard, during the various phases of a program, when required by the customer or deemed appropriate by the organization (e.g., Engineering, Manufacturing).

Although this standard is focused on variation control of KCs for manufacturing and maintenance activities, this standard can also be used as a model for other characteristics, such as those that are related to customer satisfaction (e.g., cost, on-time-delivery).

0.2 Application

This standard was created to provide requirements for the variation management of KCs when contractually invoked at any level of the supply chain. This standard can also be used as guidance within the aviation, space, and defense industry in the control of KCs. This standard can be invoked as a stand-alone requirement or used in conjunction with other IAQG standards (e.g., 9100, 9110, 9102, 9138, 9145).

For any design characteristic required by the customer (design authority or KC owner), there is a minimum probability of conformity that is needed for the product to perform its design function. Continuing to improve the process beyond that point is desirable whenever global cost-effective methods are available.

- This standard provides requirements on performing that ongoing improvement.
- The 9145 standard provides a structured framework for the product development process through the use of Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP) methodologies to ensure quality product(s) are delivered on time, while satisfying cost performance targets.

- The 9138 standard provides methods to ensure the minimum probability of conformity is achieved for each characteristic for which information is collected.
- The 9102 standard provides the method to validate with objective evidence that product realization processes are capable of producing parts and assemblies that meet engineering and design requirements.

The relationship between these standards is conceptually illustrated in Figure 1, making the link with the development milestones and 9145 process phases, starting with conceptual product needs and extending throughout the product life cycle.

- The sooner KCs are identified and put under production control, the sooner the organization can start the capitalization and optimization of the processes.
- Prior to the end of 9145 Phase 4 (Product and Process Validation), 9103 methods are used to verify the capability of the production processes prior to on-going production.
- By the end of 9145 Phase 4, the design authority has concluded that all applicable customer commitments have been satisfied in the design of the product and that the production processes “consistently” produce conforming product. This “consistent” production can be represented by a probability of conformity value in delivered product above the minimum that is acceptable to the design authority. Where 9138 applies, that minimum value is designated the Initial Reliability Requirement (IRR).
- During 9145 Phase 5 (On-Going Production, Use, and Post-Delivery Service), the focus of 9103 is to further improve the manufacturing or maintenance process maturity, reduce the cost of variation to the producer, and increase the probability of conformity rate in delivered product while remaining under the global cost-effectiveness limit (the point at which further improvement opportunities cost more than the improvement returns). This limit may evolve as more cost-effective improvements are discovered.

NOTE: The actual duration of each phase will differ depending upon the scope and timing of the specific product and/or product development project.

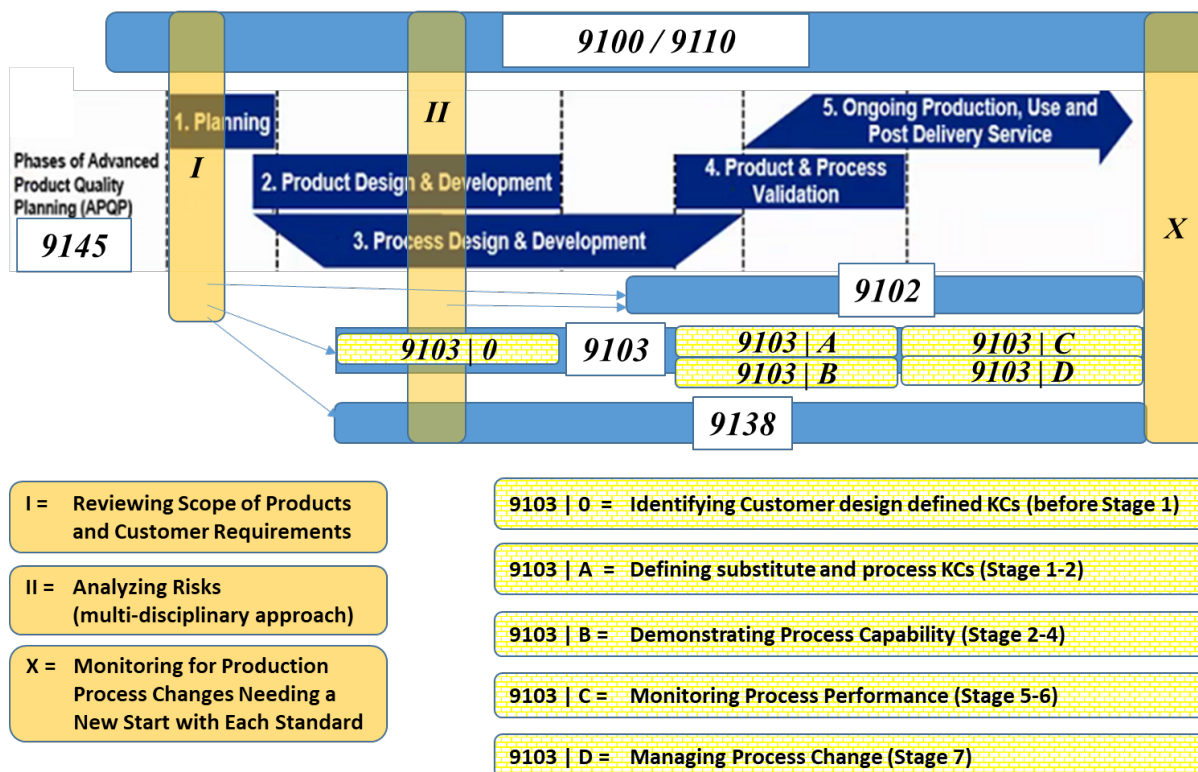


Figure 1 - Relationship for 9103 among other IAQG standards



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1. SCOPE

This standard is primarily intended to apply to new parts and products intended to be produced in an on-going production phase, but can also be applied to parts currently in production (e.g., manufacturing, maintenance). The standard is applicable to all production processes that influence the variation of KCs, as well as maintenance and service processes in which KCs are identified. It applies to organizations for assemblies and all levels of parts within an assembly, down to the basic materials including castings and forgings, and to organizations that are responsible for producing the design characteristics of the product.

The variation control process begins with product definition, typically stated in the design documentation (e.g., digital model, engineering drawing, specification) which identifies KCs, and leads to a variation management process for those KCs. This process may also be used for producer-identified KCs (e.g., process KCs, additional/substitute product KCs).

Producers and their subcontractors are responsible for flow down of the standard requirements to those external providers, who produce design characteristics and provide production and service provisions, to ensure that KCs conform to the customer's requirements.

1.1 Purpose

This standard is designed to drive the improvement of manufacturing and maintenance processes through adequate planning and effective management of KC variation. This focus is intended to improve uniformity (less variation or minimum variation of product KCs) and acceptance probability of the end-product.

NOTE: Control of a product or process KC per this standard does not constitute, nor imply, acceptance of the resulting product. If variation management, under this standard, is to be part of an acceptance decision, the requirements need to be specified in the applicable product acceptance plan or contract.

1.2 Convention

The following conventions are used in this standard:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

2. REFERENCES

The following documents should be considered for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. When a conflict between this document and the referenced standards exist, the requirements of this document shall take precedence. Further bibliographical information supporting 9103 implementation may be found in Appendix A.

9100*	Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations
9101*	Quality Management Systems – Audit Requirements for Aviation, Space, and Defense Organizations
9102*	Aerospace First Article Inspection Requirement
9110*	Quality Management Systems – Requirements for Aviation Maintenance Organizations

- 9138* Aerospace Series – Quality Management Systems Statistical Product Acceptance Requirements
- 9145* Aerospace Series – Requirements for Advanced Product Quality Planning and Production Part Approval Process

IAQG Supply Chain Management Handbook (SCMH) – (refer to IAQG website - <https://iaqg.org/tools/scmh/>)

* As developed under the auspice of the IAQG and published by various standards bodies [e.g., ASD-STAN, SAE International, European Committee for Standardization (CEN), Japanese Standards Association (JSA)/Society of Japanese Aerospace Companies (SJAC), Brazilian Association for Technical Norms (ABNT)].

- AS13006 Process Control Methods
- ISO 3534-2 Statistics – Vocabulary and symbols – Part 2: Applied statistics
- ISO 9000 Quality management systems – Fundamentals and vocabulary
- ISO 22514-7 Statistical methods in process management – Capability and performance – Part 7: Capability of measurement processes

3. TERMS AND DEFINITIONS

Definitions for general terms can be found in ISO 9000 (e.g., customer) and the IAQG International Dictionary (located on the IAQG website). An acronym log for this document is presented in Appendix B. For the purpose of this standard, the terms and definitions stated in 9100 [particularly Critical Items (CIs) and Special Requirements], in 9101 (e.g., containment), and the following apply:

3.1 Common Cause

The usual, historical, quantifiable variation in a process characterized by phenomena constantly active in the process, probabilistically predictable, and lacking significant high or low values.

NOTE: Common cause may also include irregular, but predictable variation within a historical experience base.

EXAMPLE: The variation caused by inappropriate/insufficient procedures, designs, and facilities, which may result from current limited know-how, technical conditions and technologies, awareness, etc. (e.g., poor design, poor maintenance of machines, lack of clearly defined standard operating procedures, poor working conditions, dirt, temperature, machines not suited to the job, substandard raw materials, measurement error, vibration in industrial processes, insufficient training).

3.2 Control Plan (CP)

A documented description linking manufacturing or maintenance process steps to key inspection and control activities. The intent of a CP is to control the product design characteristics and process variables to ensure product quality.

3.3 Design Characteristics

Those dimensional, visual, functional, mechanical, cosmetic, and material features or properties, which describe and constitute the design of the article, as specified by design definition file requirements.

NOTE 1: Design characteristics can be measured, inspected, tested, or verified to determine conformity to the design requirements.

NOTE 2: Dimensional features include in-process locating features (e.g., target-machined or forged/cast dimensions on forgings and castings, weld/braze joint preparation necessary for acceptance of finished joint). Material features or properties may include processing variables and sequences, which are specified by the design definition file (e.g., heat treat temperature, fluorescent penetrant class, ultrasonic scans, sequence of welding and heat treat). These provide assurance of intended characteristics that could not be otherwise inspected.

3.4 Design Documentation

Documentation supporting engineering definition/specification, which fully define the product, including physical or electronic/digital drawings, electronic/digital models, firmware/software, or other associated information. This includes records of authorized engineering changes not yet incorporated into the released engineering definition/specification.

3.5 Failure Mode and Effects Analysis (FMEA)

A structured method for analyzing risk by ranking and documenting potential failure mode(s) in a system, design, or process. The analysis includes:

- Identification of potential failures and their effects;
- Ranking of factors (e.g., severity, frequency of occurrence, detectability of the potential failures); and
- Identification and results of actions taken to reduce or eliminate risk.

NOTE 1: The FMEA assists in the identification of CIs as well as key product and process characteristics, helps prioritize action plans for mitigating risk, and serves as a repository for lessons learned. FMEA examples include: system FMEA, interface FMEA, Design Failure Mode and Effects Analysis (DFMEA), and Process Failure Mode and Effects Analysis (PFMEA).

NOTE 2: PFMEA is a means of analysis using the FMEA methodology and DFMEA results, when available, to identify and analyze potential failures and their effects during manufacturing or maintenance processes, and to take preventive actions and controls to reduce or eliminate risks.

3.6 Key Characteristic (KC)

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. [SOURCE: 9100]

NOTE 1: Other identified characteristics may be included in order to master interfaces, functional characteristics, and the process capability and potential process drift.

NOTE 2: KC attributes can include:

- A characterization (e.g., nominal value with associated tolerances);
- A ranking of the effect of variation (e.g., significant severity of the effect of a potential failure mode identified by design risk analysis); and
- The acceptable occurrence of non-detected nonconformities.

NOTE 3: Validation of KCs includes in particular process dispositions and control/inspection operations.

NOTE 4: Product KCs are those selected measurable geometrical, material properties, functional, and/or cosmetic features of a product, whose variation control is necessary in meeting customer requirements, enhancing customer satisfaction, or requires specific actions for the purpose of controlling variation.

NOTE 5: Process KCs are those selected measurable characteristics of a manufacturing process whose control is essential to manage variation of product KCs; for example, production variables (e.g., temperature, time, pressure, voltage, operating amperage, vacuum degree).

NOTE 6: Substitute KCs are “child” product KCs derived from the “parent” KC in order to guarantee the “parent” needs (substitution characteristic), if the “parent” KC cannot be directly controlled or guaranteed by the production process through process KCs. Substitute KCs are identified when a customer-defined KC is not readily measurable within the manufacturing/maintenance setting and other characteristics are needed to be controlled to ensure conformity.

NOTE 7: A KC is measurable, if information on its condition can be detected. The variation in the frequency of an attribute condition can be managed using this standard.

3.7 Key Characteristic (KC) Owner

The organization that defines the product and process KCs, and recognizes the reasons for their selection.

NOTE 1: Typically, KC owner responsibilities are held by internal/external customer design, quality, manufacturing, or maintenance engineering, and identified by a Multi-Functional Team (MFT) through risk analyses.

NOTE 2: Product KC owner is the design authority responsible for the product definition.

NOTE 3: Process KC owner is the producer. Producers may determine additional relevant process KCs to establish variation control of customer-defined product KCs, based on the information and data collected during the manufacturing or maintenance processes. They could also define a substitute KC to achieve variation management of a not readily measurable customer-defined KC.

3.8 Measurement System Analysis (MSA)

A study of the effects of selected elements of a measurement process (i.e., people, machines, tools, methods, materials, environment) on the accuracy, precision, and uncertainty of measurement. [SOURCE: 9145]

NOTE: MSA is the evaluation of variation of the measurement system in comparison to product performance variation [e.g., Gage Repeatability and Reproducibility (Gage R&R), attribute agreement, bias assessment, stability assessment, linearity assessment]. The purpose of a MSA study is to ensure the information collected is a true representation of what is occurring in the activity/process being measured. Without a MSA, there is a risk of making decisions based on an inaccurate ‘picture’ of product performance.

3.9 Multi-Functional Team (MFT) [also commonly referred to as Cross-Functional Team]

Team composed of representatives from the functions needed to perform the KC identification and management process [e.g., Design (product KC owner), Dependability (reliability, availability, maintainability) and Safety, Production (process KC owner)].

3.10 Process Capability

The ability of a process or product to consistently meet specification or customer requirements.

NOTE 1: The process capability is often expressed as a capability index (e.g., Cpk, Ppk).

NOTE 2: A detailed definition may be found in ISO 3534-2.

3.11 Producer

The organization that identifies process KCs and uses KC data to maintain, monitor, and improve the manufacturing and maintenance processes.

NOTE 1: The product KC owner may also identify and communicate process KCs.

NOTE 2: The producer can be an internal or external provider.