AEROSPACE STANDARD

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Superseding AS9103A

Technically equivalent writings 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.

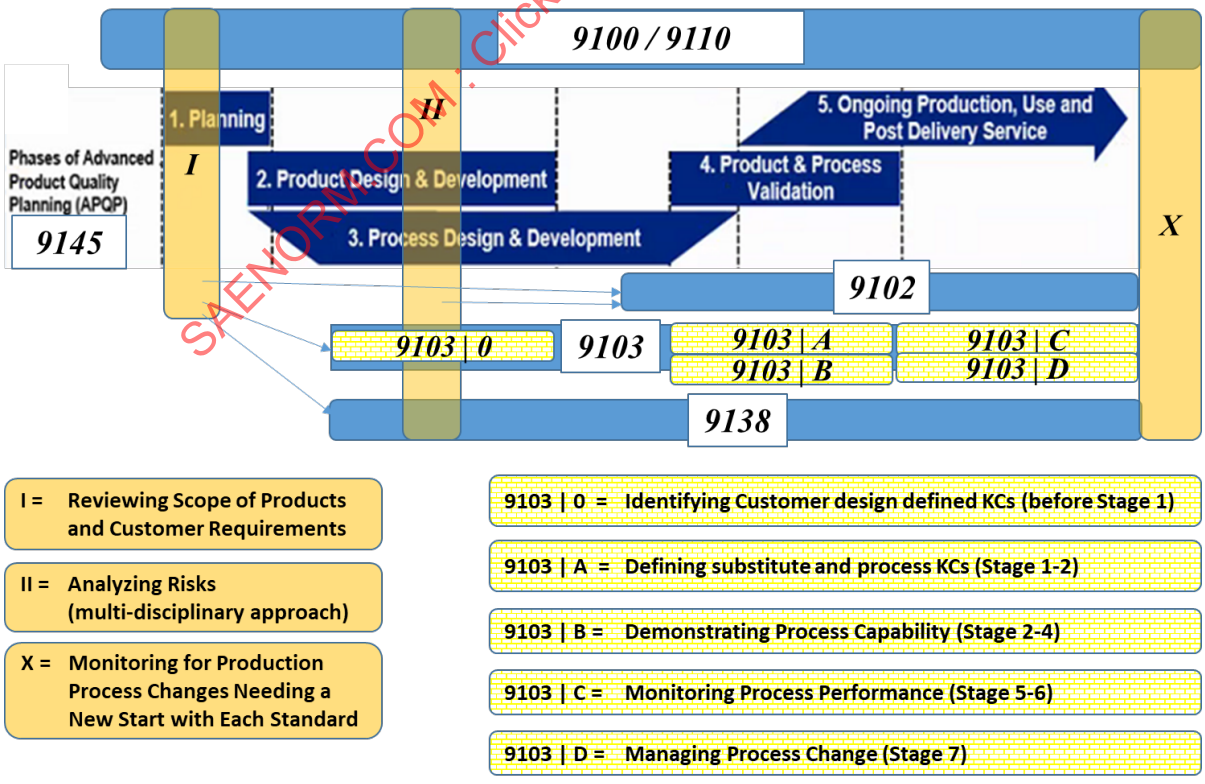

Figure 1 - Relationship for 9103 among other IAQG standards

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.

3.12 Reaction Plan

A plan that will be applied or invoked when the manufacturing or maintenance process does not show to be robust or healthy.

NOTE: Typically, the reaction plan documents, at a minimum, contain the following information:

- Description of unstable or incapable process no matter whether the characteristic of the affected part is within the tolerance or not;
- Containment measures or immediate actions taken to stop the extension of the undesired observations through the allocation of better resources to the affected process, including 100% inspection to keep the process on-going without the risk of delivering nonconforming product to customer;
- Cause analysis, including tentative determination of the cause, supporting the identification of the root cause;
- Taking appropriate corrective actions;
- Conducting the verification of the effectiveness of corrective actions taken; and
- Returning to controlled production after closing the corrective action.

3.13 Special Cause (also commonly referred to as Assignable Cause)

Variation characterized by unanticipated emergent or previously neglected phenomena within the system that is probabilistically unpredictable (e.g., machine start-up, faulty controllers, machine malfunction, computer crash, poor batch of raw material, power surges, broken part, lack of awareness, operator absent).

4. GENERAL REQUIREMENTS

4.1 Flow Down of Product Key Characteristics

4.1.1 When determining product KC requirements, the producer shall communicate with the customer to ensure that the customer product KCs are defined and understood.

NOTE: By identifying the KCs of a product or process, work can focus on the characteristics where expected variation most influences manufacturability and the cost of quality. Specific focus on product KC identification, as early as possible during development, is important.

4.1.2 The producer shall ensure that product KCs are flowed down to applicable internal and external providers by the use of appropriate design documentation.

4.1.3 The producer shall define substitute KCs necessary for production by appropriate tools (e.g., through lessons learned, function analysis, design risk analysis or other risk assessments) in the following cases:

a. The customer did not define the product KCs, but defined the product feature or attribute control requirements for the producer (external provider or process KC owner); and

b. An external provider encounters variation effects that affect product quality.

NOTE: There is a close link between the process risk analysis and design risk analysis. The design risk analysis identifies potential failure modes, and the severity of the effects of the failure modes should be used as an input to the process risk analysis. Updates to either may impact the other and should be taken into account.

4.2 Preparation of Control Plan Inputs and Outputs

4.2.1 The producer shall:

a. Develop CPs to achieve customer satisfaction with the delivered product quality.

NOTE 1: The APQP product development planning process is defined in the 9145 standard.

NOTE 2: Statistical product control methods related to product KCs are described in the 9138 standard.

b. Determine a process for reviewing and updating the CP when changes occur (e.g., affecting product, production process, measurement, logistics, supply sources, process risk analyses). This includes seeking customer approval, when required.

NOTE: Reviews and updates of Process Flow Diagrams (PFDs), PFMEAs, and CPs should also capture process and inspection changes, and new knowledge gained during production (e.g., lessons learned from production stops or delays, nonconformity, product quality escapes, inspection data, root cause corrective action investigations on current or similar products, scrap data).

4.2.2 To obtain the information needed for the development of a CP, the producer shall:

a. Establish a process flow and conduct the process risk analysis (e.g., PFMEA or equivalent causal analysis) representing the corresponding manufacturing or maintenance activities.

b. Identify the design documentation requirements and associated process flow, as well as the design and process risk analyses outputs.

c. Document the engineering specifications, product KCs, process KCs, and control methods in the CP where each KC is controlled or measured.

d. Trace the process step in the manufacturing or maintenance plan where each KC is controlled or measured (e.g., with an appropriate visibility symbol).

e. Choose the proper process monitoring or control methods to control the KCs.

NOTE: Evidence of sufficient process control may include, but not be limited to procedures and records of configuration control of process inputs, elements, or characteristics that affect conformity of products to specifications or Statistical Process Control (SPC) methods with a CP, and audit records showing that the process is consistently practiced (as defined).

4.3 Conditions for Performing Statistical Process Control

4.3.1 Where non-SPC control methods (e.g., tooling, error-proofing) are used to ensure process control and capability, measurable evidence shall demonstrate that the controls are effective.

4.3.2 Where SPC is chosen as the method for the control of KCs, the following requirements shall be met:

a. The process shall be statistically stable and capable (i.e., with Cpk $\geq$ 1.33) or as defined by or agreed with the customer.

NOTE: Process capability indexes only refer to processes in statistical control and cannot be used to describe the output of a process which is not stable. A low Cp indicates a dispersed production. A process is considered capable, if its Cpk meets or exceeds the target of 1.33 or the targeted value as defined by or agreed with the customer. Other comparable measures of process capability may be used (e.g., process performance index Ppk).

b. The process capability index (e.g., Cp, Cpk) shall only be calculated and established when the process is shown to be stable and in statistical control through use of appropriate statistical methods and/or control charts.

NOTE: Information on process stability and capability may be found in the 9138 standard. Further information for the calculation of process capability indices and the calculation of measurement uncertainty may be found in ISO 3534-2 and ISO 22514-7.

4.4 Application of Switching Rules

4.4.1 If the process performance deteriorates such that it's no longer meeting minimum capability requirements, the producer or process KC owner shall implement the customer approved acceptance sampling plan or 100% inspection of the product until the cause has been identified, corrected, and process capability and control have been re-established and revalidated.

NOTE: For cases with evaluation uncertainty, further or repeated inspection may be necessary.

4.4.2 When process capability is used to justify reduced frequency of inspection, the probability of nonconformity shall be determined using industry recognized statistical methods.

4.5 Restrictions of Statistical Process Control

4.5.1 When KCs related to safety aspects are identified in the design documentation, the customer-identified product KCs shall not be accepted using sampling or other statistical product acceptance methods, unless specific justification by the product KC owner is granted from the customer (e.g., customer approved procedure, method for acceptance is defined in the design documentation).

4.5.2 Where it is impossible or prohibitively expensive to satisfy the stability and capability requirements for a process, the exceptions shall be documented by the producer and the customer informed.

4.5.3 The producer shall establish an internal assessment process of product and process KCs to verify on-going variation reduction and evaluate related continual improvement efforts.

4.6 Personnel Competence and Training

4.6.1 To ensure effective KC variation management and control methods, the producer shall be capable in using the tools and methodologies defined within this standard.

4.6.2 The producer shall ensure that personnel involved in the identification, control, documentation, and approval of KCs meet the training requirements of the Aerospace Quality Management system (AQMS), and have a good knowledge of the customer's requirements for the application of process control, which affect product quality.

4.6.3 The producer shall have documented processes for delivering training identified by the organization or the customer to personnel involved in the identification, control, documentation, and approval of KCs.

NOTE: The following training key focus areas may reflect the process control aspects addressed within this standard:

a. The importance of process control.

b. Process control in context of quality planning (e.g., linkage of process risk analysis, CP, and work instructions).

c. Selection of process control methods.

d. Data collection (e.g., time sequence, reliable measurement system, non-biased data, sample size).

e. Process capability analysis tools.

f. Root cause analysis, problem solving, and process improvement basics.

g. Application of control chart tools.

h. Application of error-proofing principles, devices, and strategies.

i. Other optional relevant techniques [e.g., Design of Experiments (DOE), hypothesis testing, MSA].

4.7 Key Characteristic Variation Management and Control Documentation

4.7.1 The producer shall have documented processes at the company or program level for KC variation management and control, which shall include but not be limited to the following, where applicable:

a. Identification and control of product KCs;

b. Process risk analyses and approval of CPs;

c. Defined responsibilities, escalation process definition, and flow of information, when necessary, including top management and customer notification;

d. Training identified by the organization or the customer for personnel involved in the identification, control, documentation, and approval of KCs (see 4.6.3 NOTE);

e. Approval of product or process changes, prior to implementation, including evaluation of potential effects on the defined KCs due to these proposed process and product changes;

f. Transfer of requirements regarding defined KCs throughout the supply chain;

g. Reaction plan;

h. Plan to achieve containment; and

i. Other relevant information necessary for product and process improvement.

5. PROCESS MODEL FOR VARIATION MANAGEMENT OF KEY CHARACTERISTICS

This section describes the process model that shall be used in fulfilling the general requirements of this standard. The model consists of seven process stages, starting with the definition of product and process related KCs, whose control is achieved through KCs variation management; ending with the monitoring of product manufacturing or maintenance process performance (see Figure 2).

This process model shall be tailored to needs (e.g., in case of work transfer, the review of product KCs may be out of scope and the process may start after the process risk analysis step); furthermore, in case of APQP application, additional process steps (as defined in the 9145 standard) may be applicable.

5.1 Stage 1: Conduct Product Performance and Key Characteristics Review

5.1.1 Reviewing Customer Provided Design Documentation to Identify Product Key Characteristics

a. The producer shall establish a MFT consisting of Program Management, Engineering, Production (manufacturing and maintenance), Procurement, and Quality, as applicable, to review the customer provided design documentation to identify the customer-defined KCs.

NOTE: The MFT should have an understanding of the manufacturing or maintenance processes, and be capable of reviewing the customer's requirements, including any associated product performance requirements.

STAGES	INSIGHTS
Stage 1 Conduct Product Performance and Key Characteristics	After design documentation release by the customer, review of product KCs is performed by a MFT to encompass product, process, and customer requirements in the consideration of a suitable manufacturing or maintenance control method.
Stage 2 Define the Plan to Ensure a Capable Process	In support/consideration of the identified KCs, a manufacturing or maintenance process is designed to be capable of meeting today's needs and future aspirations. Without this foresight, the level of variation inherent in the process may become a limiting factor to meeting customer expectations and the cost efficient operation of the process.
Stage 3 Operate the Process on Trial Basis to Generate Data	Operate the manufacturing or maintenance process ensuring the data collection method has been planned to provide information about the variation of process parameters and resulting product variation relevant to the KCs. Without careful consideration of the process variation at this stage, later analysis of data could miss vital information as to the 'real' process performance.
Stage 4 Analyze Data for Action	Skilled interpretation of the data provides evidence of the process performance and therefore, product variation. Informed decisions based on objective information can help to prevent 'risks' in the hands of the producer and more importantly - the customer.
Stage 5 Take Action from Process Performance Study	Information generated is of minimal use to improving process performance and product quality, unless acted upon in a controlled and appropriate manner. This too needs careful consideration to identify isolated incidents and avoid process tampering to prevent more uncertainties being introduced.
Stage 6 Continue to Monitor the Process	Monitoring process or product KCs that satisfy customer expectations can help to identify the need for improvement. Monitoring continued process performance is vital to know when undesirable variation may occur, before it is detrimental to the customer.
Stage 7 Manage Process Change No Yes	Whatever the reason for considering a process change (e.g., natural process degradation, changing customer requirements, improvement), any decision needs to be substantiated with data to enable the implementation of an effective action plan.

Figure 2 - Key characteristics variation management model

5.1.2 Determining Process Key Characteristics

a. The producer shall perform process risk analysis (e.g., PFMEA) or use other methods to determine relevant process KCs in order to establish variation control of product KCs.

NOTE: The KC identification process should include the following inputs:

- Lessons learned are the first input to consider, especially when establishing the initial process KC lists.
- Function analysis is also a fundamental input as it allows for the identification of process performance main drivers.
- Process flow and key points in the manufacturing or maintenance processes.

5.1.3 Identifying Substitute Product Key Characteristics

a. The producer shall determine substitute product KCs based on the information and data collected during the manufacturing or maintenance processes. This information or data shall include, but are not limited to the following:

    1. Rejections and customer complaints;
    2. Form, fit, and function;
    3. Manufacturability;
    4. Service life; and
    5. Other needed information.

b. If substitute KCs are used, the producer shall demonstrate an adequate justification depicting the relationship/association of the substitute KCs to the customer-defined KCs.

NOTE 1: The producer may determine lower-level or substitute KCs to control variation of higher-level KCs.

NOTE 2: The purpose for variation management of a measurable substitute KC is to achieve variation management of the not readily measurable customer-defined KC. Variation of the measurable substitute KC should correlate with causality to the not readily measurable customer-defined KC. This correlation is reasonably expected to continue even when the parent KC is out-of-control.

c. The producer defined substitute product KCs shall be documented in the CP and communicated with the customer, as necessary.

5.1.4 Releasing and Maintaining Identified Key Characteristics

a. The producer shall establish a list of KCs after the review of the customer's provided design documentation, including identified product KCs, additional substitute KCs, and/or relevant process KCs.

b. Each KC in the list shall, at a minimum, include the following information:

    1. Applicable drawing/specification number;
    2. Associated part name;
    3. Product features to be controlled;
    4. Assigned KC number; and
    5. Area where KC is verified.

c. The producer shall release the approved list of KCs to the appropriate process KC owner(s) for KC variation control.

d. The producer shall justify any addition or removal of product or process KCs to the customer (i.e., design authority or KC owner), based on the results of monitored product manufacturing or product maintenance process performance.

5.1.5 Outputs of Stage 1

a. Stage 1 outputs shall include at a minimum:

1. Identified KCs necessary to meet the customer's requirements;

2. Cause/effect analysis;

3. Substitute KCs associated with customer-defined KCs; and

4. Process KCs.

5.2 Stage 2: Define the Plan to Ensure a Capable Process

5.2.1 Preparing the Control Plan

a. The producer shall define the requirements for the preparation of a CP to support the monitoring of product and process conformity.

b. The preliminary CP shall include, at a minimum, the elements defined in Section 6.

5.2.2 Developing the Manufacturing or Maintenance Process Flow Diagram

a. The producer shall generate a process flow that includes all manufacturing and maintenance operations in sequential order. This encompasses alternate processes and movement of product to and from external operations.

NOTE 1: Alternate processes are different processes used to achieve the same output (e.g., backup equipment, secondary source, change in sequence).

NOTE 2: Refer to the SCMH for PFD template.

b. The producer shall develop a process flow for each part number or process family, and indicate, with appropriate symbols, process steps where each product KC is produced and measured as well as the process KCs defined in the design documentation.

c. The producer shall identify sources of variation that affect product KCs. Knowledge of the existing process and the customer's requirements shall be considered.

5.2.3 Developing a Manufacturing or Maintenance Process Risk Analysis

a. The producer shall perform a risk analysis of the manufacturing or maintenance process, and identify mitigation plans for high risks (e.g., using the PFMEA methodology or equivalent causal analysis, unless an alternate process risk analysis method is required and/or approved by the customer):

1. Including all operations identified in the process flow as well as details of the steps within each operation; and

2. Identifying substitute product KCs and/or relevant process KCs, in addition to those defined in the design documentation, in order to establish variation control of product KCs.

b. The process risk analysis shall be used to identify process KCs, based on high-risk severity and occurrence levels, as defined by the customer's requirements and/or organizational policy.

c. The process risk analysis severity, occurrence, and detection rankings shall be reviewed and actions considered for reprioritization when:

    1. Changes are made to the process or product;

    2. Rate of failure occurrence is not reflective of actual frequency (e.g., nonconformity has occurred that was not previously listed); or

    3. New controls are implemented or existing controls modified.

d. Product and process KCs shall be traceable from their originating document through the process flow, process risk analysis, and CP. Traceability may be achieved by using the same characteristic identifiers in all documents.

5.2.4 Establishing the Manufacturing or Maintenance Process

a. The producer shall maintain and improve process performance that generates the KC.

b. The producer shall define a manufacturing or maintenance process based on a new or an existing process flow. This includes the identification of elements that influence the variation of KCs (see 5.2.2.c).

c. The producer shall review processes that create or affect KCs to identify potential failure modes, significance of effects, and probability for occurrence of cause. When effect and/or occurrence are significant, actions need to be taken to prevent the cause or detect and contain the failure mode.

d. The producer shall develop work instructions and measurement instructions in accordance with the MSA study to manage associated sources of variation.

5.2.5 Updating the Control Plan

a. The producer shall update the CP after completing activities for this stage (see Section 6).

5.2.6 Outputs of Stage 2

a. Stage 2 outputs shall include at a minimum:

    1. Process flow of the manufacturing or maintenance process (or equivalent documentation);

    2. Identification of the process owner;

    3. Potential sources of variation (e.g., MSA selection, process risk analysis results);

    4. Manufacturing or maintenance plan or work instructions;

    5. Measurement instructions; and

    6. CP.

5.3 Stage 3: Operate the Process on Trial Basis to Generate Data

5.3.1 Developing the Data Collection Plan

a. The producer shall create a data collection plan(s) that reflect the sources of variations, for all KCs.

b. The producer shall determine the type of control chart to be used for data collection.

c. The plan shall define who, what, where, frequency, and how many parts shall be included and under what conditions the data shall be collected.

5.3.2 Producing Trial Parts

a. The producer shall manufacture trial parts according to defined work instructions.

b. The trial parts shall be manufactured and configuration controlled in a representative or normal production environment using production type tooling and processes.

NOTE 1: The producer should perform graphical assessment (e.g., a run chart or pre-control chart) during production runs to view process behavior and recognize where immediate actions are needed, prior to performing statistical data analysis.

NOTE 2: Feedback from a production process verification [often referred to as a First Article Inspection (FAI); reference 9102] should be analyzed, when trial parts are first produced in the actual production environment.

NOTE 3: Operation of the process in Stage 3 may differ from operation of the process in Stage 6, because during Stage 3 it may be helpful to intentionally run the process under conditions that validate the allowed range (and slightly beyond) of controllable variables (e.g., with a DOE). Once it is established that the process works as designed throughout the accepted ranges of its controllable variables, then the goal shifts to fixing the levels of the controllable variables so as to achieve minimum variation in the product.

NOTE 4: It may be required by the customer that the Cpk be above 1.67, during the trial production, to ensure that the subsequent production process can maintain the process capability (see 4.3.2.a).

5.3.3 Conducting a Measurement System Analysis Study

a. In the following cases, a MSA study (e.g., Gage R&R) shall be conducted to determine the gage capability:

   1. As part of new product or tool introduction, after monitoring and measuring device has been calibrated, but before it is put into use for measuring KCs.

   2. KC associated production process is not capable (see 4.3.2.a) and no cause can be found.

   3. An out-of-control condition occurs, but no cause can be assigned.

NOTE 1: Poor measurement systems may reduce the ability to demonstrate control or capability, and make investigation into the sources of variation difficult; therefore, the most appropriate measurement system should be used.

NOTE 2: Gage study may use gage capability/tolerance or gage capability/process variation as criteria. The customer's identified criteria should take precedence, when the method "gage capability/tolerance" is used. The variation of measurement system should not be more than 10% and never exceed 30% of the engineering tolerance.

NOTE 3: Applicable MSA studies can be established using various methods (e.g., bias studies, Gage R&R, repeatability study, measurement uncertainty analysis, attribute agreement analysis). It's recommended that the measurements should not consume more than 10% of the tolerance or that the ratio of the characteristic tolerance to measurement uncertainty should be at a minimum 10:1, although greater measurement uncertainty is tolerated, when necessary. For improvement purposes under this standard, greater values of measurement uncertainty make the finding of improvement opportunities slower and more difficult.

b. The producer shall verify through MSA studies that the measurement systems are suitable to evaluate product and process KCs.

c. The producer shall demonstrate that all measurement methods and supporting checking tools included in the CP are suitable, capable, and support the customer demand rate.

d. A MSA study shall be performed on the measurement methods for product and process KCs identified in the CP, as applicable (e.g., when new tools have been purchased).

e. Once an improved measurement system is put into service, new measurements shall be conducted to verify that the process is in statistical control and has the required capability.

f. When MSA results do not satisfy the internal and/or the customer's acceptance criteria, the producer shall establish and implement corrective action plans.

5.3.4 Collecting Data to Monitor Process Performance

a. The producer shall:

1. Collect the data according to the related CP;

2. Collect the data per the defined collection plan, at the controlled operation step;

3. Record the data collected, as required; and

4. Transfer the data to SPC software, when required by the customer.

NOTE: Any deviation to the data collection plan needs to be documented.

5.3.5 Plotting Collected Data or Summary Statistics on Control Chart

a. The producer shall determine and plot the collected data or summary statistics on applicable control charts according to the related CP.

b. Appropriate control limits and rules shall be in place to separate common cause from special cause variation. Such limits shall be based on data from the process and not influenced by product requirements (e.g., engineering tolerances).

c. Mixed KC populations with significantly different variability shall not be combined on the same control chart.

NOTE 1: SPC is the preferred method for variation management. The statistical method to be applied may depend on the type of data to be collected (i.e., variable or attribute data) and the process maturity (e.g., run-charts until control limits are established).

NOTE 2: Commonly or popularly used SPC charts are given as follows:

- Traditional X-bar and R-chart, when production rate is high and one KC for one part number needs to be under monitoring;
- Traditional X-bar and S-chart, its application conditions are the same as those for Traditional X-bar and R-chart;
- Individual X- Moving Range chart, when production rate is low and one KC for one part number needs to be under monitoring;
- P-chart (percent defective), when production rate is high and defectives on only one type of unit are counted;
- NP-chart (number defective), when production rate is high and defectives on only one type of unit are counted;
- C-chart, when different types of defects on one type of unit are counted; and
- U-chart, when average number of defects per unit is calculated.

For more specific applications using other SPC charts, refer to ISO 22514-7 and AS13006.

NOTE 3: Measurements used in industry recognized statistical methods to calculate control limits and centerline typically use a minimum of 20 measurements in order to obtain rational control limits.

NOTE 4: Samples corresponding to out-of-control plot points should be removed from the control limit calculations, but should remain on the chart itself. For any point removed from the calculation, an additional sample may need to be collected to maintain the number to calculate the control limits.

NOTE 5: Once control limits have been established, these control limits should be recalculated whenever substantial changes in the process are evident (e.g., configuration change, process method change, inspection method change), and the control charts should be annotated to indicate at what point the change took place and to record the nature of the process change.

NOTE 6: The type of risk to be mitigated may justify the need for more than one process control method.

5.3.6 Updating the Control Plan

The producer shall update the CP, as required.

5.3.7 Outputs of Stage 3

a. Stage 3 outputs shall include at a minimum:

    1. Data collection plan;

    2. Results of MSA study;

    3. Control chart; and

    4. Updated CP for changed or new information.

5.4 Stage 4: Analyze Data for Action

5.4.1 Reviewing the Control Chart to Monitor Process Performance

a. The producer shall review control charts to determine if the process is stable.

b. The producer shall calculate process capability and provide evidence to demonstrate statistical reasoning and justification, in addition to the calculation method.

c. The process capability index (e.g., Cp and Cpk) shall be calculated only when the process is stable.

d. If the process is not stable, the nonconformity control process shall apply (i.e., the producer shall investigate using appropriate problem solving tools to determine and verify the root cause). Investigation results shall be documented.

e. During operational phases, the producer shall monitor product and process KCs, as defined in the CP, in order to detect and correct any deviation or out of family behavior (e.g., shift in the mean).

f. The producer shall re-evaluate process KCs, based on understanding of the observed process behavior, to determine if any KCs should be added or do not apply.

5.4.2 Periodically Analyzing the Data to Ensure On-Going Process Capability

a. The producer shall periodically analyze the data produced from monitoring of KCs to ensure on-going process capability.

b. The producer shall maintain the minimum acceptable capability index for each identified KC (refer to 9138 and 9145, as appropriate).

5.4.3 Pursuing Investigation into Out-of-Control Conditions or Sources of Variation

a. If the process shows out-of-control conditions or does not meet minimum capability requirements, the producer shall conduct an investigation and identify sources of variation in the processes that correlate to the KC.

b. These investigation findings shall be documented.

5.4.4 Updating the Control Plan

a. The producer shall update the CP.

b. Reference to associated documentation shall be included.

5.4.5 Outputs of Stage 4

a. Stage 4 outputs shall include at a minimum:

1. Process capability, including calculation method;
2. Investigation results of out-of-control points;
3. Investigation results of sources of variation;
4. New or revised KCs identified;
5. Updated process documentation; and
6. Updated CP for changed or new information.

5.5 Stage 5: Take Action from Process Performance Study

5.5.1 Applying the Control Plan's Reaction Plan to Deal with an Unstable Process

a. The producer shall deploy the CP's reaction plan when a process becomes unstable or a failure occurs, regardless of whether it is within tolerance (see Appendix C).

b. The effectiveness of corrective action taken shall be verified.

5.5.2 Performing Measurement System Analysis to Deal with Incapable Process

a. The producer shall investigate gage variation when a process is not capable or the special cause continues to be present.

b. If a MSA study has already been performed, the producer shall verify the results.

c. If the process is not capable (see 4.3.2.a) after the MSA study, the producer shall analyze the source of variation by appropriate means (e.g., brainstorming, cause and effect diagrams, other tools to systematically identify and document the cause) and further determine the most influential causes by using Pareto analysis.

d. The producer shall perform activities to reduce variation on identified product and process KCs until the required process stability and capability have been reached.

e. If a process is stable, but not capable; the producer shall:

1. Investigate sources of variability. Data should indicate if a process is not centered and/or if high variability is present.

2. Implement process control methods to reduce the common cause variation, until the capability meets the customer's requirements.

NOTE: Process control methods such as those listed in AS13006 may be used.

3. Take appropriate action(s) to improve process capability by reducing variability and aligning the process central tendency with the target specification.

f. If the process is stable, but the capability does not meet the customer's requirements, the producer shall prioritize common cause sources of variation, to identify the most influential source(s). Subsequent investigation(s) shall determine root cause(s) of this variability to improve the process to ensure the required probability of conformity.

g. If the process is stable and the capability meets the customer's requirements, then no further action needs to be taken on the process and the CP shall be finalized.

h. The producer shall maintain the degree of control and process capability.

5.5.3 Implementing the Plan to Achieve Containment

a. If after performing the previous action(s), the process is not stable or capable, the producer shall implement a plan to achieve containment (i.e., product and/or process protection) until such time that the process is proven stable and capable.

5.5.4 Updating the Control Plan

a. The producer shall finalize the CP as soon as the process is stable and capable.

NOTE: The production process verification (often referred to as FAI; reference 9102) may be used to verify that the production process is capable.

b. Whenever actions are taken that change the manufacturing or maintenance process, the producer shall take appropriate action in Stages 2 through 5.

5.5.5 Outputs of Stage 5

a. Stage 5 outputs shall include at a minimum:

1. Corrective action documentation for out-of-control points;

2. MSA study;

3. Corrective action documentation for sources of variation;

4. Containment (i.e., product and/or process protection);

5. Updated process documentation; and

6. Updated CP for changed or new information.