SLOVENSKI STANDARD
SIST EN 9103:2015

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Nadomešča:
SIST EN 9103:2008

Aeronavtika - Sistemi vodenja kakovosti - Vodenje sprememb ključnih značilnosti

Aerospace series - Quality management systems - Variation management of key characteristics

Luft- und Raumfahrt - Qualitätsmanagementsystems - Management der Veränderung der Haupteigenshaften

Série aérospatiale - Systèmes de management de la qualité - Management de la variation des caractéristiques clefs

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English Version

Aerospace series - Quality management systems - Variation management of key characteristics

Série aérospatiale - Systèmes de management de la qualité - Management de la variation des caractéristiques clefs

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Management der Veränderung der Haupteigenshaften

This European Standard was approved by CEN on 29 November 2014.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 9103:2014) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2015, and conflicting national standards shall be withdrawn at the latest by June 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 9103:2005.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Rationale

This standard was revised to coincide with the updated information presented in the International Aerospace Quality Group (IAQG) 9100-series standards (i.e., 9100:2009, 9110:2009). All other changes made to standard requirements or methods presented herein were editorial in nature.

Foreword

To assure customer satisfaction, the aviation, space, and defence 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 suppliers throughout the world and at all levels within the supply chain. Industry suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The aviation, space, and defence industry established the International Aerospace Quality Group (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 “Key Characteristic” (KC) identification, control, documentation, and approval for the industry. The establishment of common requirements, for use at all levels of the supply-chain by organizations, 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.

INTRODUCTION

General

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

The standard requires a thorough assessment of the applicable production/maintenance process with the primary goals being to control and minimize variation in characteristics generated by the process.

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.
- Process Control Documents (PCDs) or equivalent documentation that defines specific control of KCs and manufacturing/maintenance process parameters.

This standard does not:

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

Although the 9103 standard is focused on variation control of KCs for production and maintenance activities, this process can also be used as a model for other characteristics, such as those that affect cost and delivery.

Application

This standard was created to provide for a uniform process for the identification, control, documentation, and approval of KCs when contractually invoked at any level or as guidance within the aviation, space, and defence industry in the control of Critical Items (CIs). This standard can be invoked as a stand-alone requirement or used in conjunction with 9100-series standards (i.e., 9100, 9110).

1 Scope

This standard is primarily intended to apply to new parts and products, but can also be applied to parts currently in production. The standard shall be applicable to all production processes that influence the variation of KCs, as well as maintenance processes in which KCs are identified. It applies to 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.

It does not apply to lab-scale, pilot, or pre-production processes. However, particular management of some KCs might be required using other methods than those described in the standard, during these phases of a programme, when required by the customer or deemed appropriate by the organization (e.g., Engineering department requirement).

The variation control process begins with product definition, typically an engineering drawing or specification which identifies KCs, and leads to a variation management program for those KCs. This process may also be used for producer-identified KCs.

Producers and their subcontractors shall be responsible for flow down of the requirements of the applicable revision of this standard to subcontractors, who produce design characteristics, and for ensuring that KCs conform to customer 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. The KC focus is intended to improve confidence for part features whose variation has a significant influence on to end-product form, fit, performance, service life, and producibility.

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 must be specified in the applicable product acceptance plan or contract.

1.2 Convention

The following conventions are used in this standard:

- The words "shall", "will", or "must" indicate mandatory requirements.
- The word "should" indicates a requirement with some flexibility allowed in compliance methodology.
- Producers choosing other methods to satisfy a "should" shall be able to show that their approach meets the intent of the requirements of this standard.
- Words "typical", "example", "for reference", "may", or "e.g." indicate suggestions given for guidance only.
- "NOTES" are used for additional clarification.
- Words or phrases with specific meaning pertaining to this document are defined in Clause 3, Terms and Definitions.

2 Normative references

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

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (inside USA and Canada) or 724-776-4970 (outside USA), www.sae.org.

AS 9100, *Quality management systems — Requirements for aviation, space and defence organization*

AS 9102, *Aerospace first article inspection requirement*

AS 9110, *Quality management systems — Requirements for aviation maintenance organization*

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

2.1 Related publications

The following publications are provided for information purposes only and are not a required part of this SAE Aerospace Technical Report.

ISO 9001:2008, *Quality management systems — Requirements*

ISO 9004:2009, *Managing for the sustained success of an organization — A quality management approach*

3 Terms and definitions

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

3.1
Critical Item (CI)
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 include safety CIs, fracture CIs, mission CIs, KCs, and maintenance tasks critical for safety.

3.2
customer
the organization which identifies CIs and/or provides part or system KCs via engineering drawings, specifications, or purchase order/contract requirements. For example, a customer may be an internal engineering department for a company which has design authority, in addition to the external customer who specifies system KCs.

3.3
Key Characteristic (KC)
an attribute or feature whose variation has a significant influence on product fit, performance, service life, or producibility; that requires specific action for the purpose of controlling variation (reference 9100 and 9110).

This definition is further explained as follows:

KCs for a part, subassembly, or system are those selected geometrical, material properties, functional, and/or cosmetic features; which are measurable, whose variation control is necessary in meeting customer requirements and enhancing customer satisfaction.

Process KCs are those selected measurable characteristics of a process whose control is essential to manage variation of part or system KCs.

Substitute KCs may be identified when a customer-defined KC is not readily measurable within the production/maintenance setting and other characteristics may need to be controlled to ensure conformance.

NOTE Design output can include identification of critical items that require specific actions to ensure they are adequately managed. Some CIs shall be further classified as KCs because their variation needs to be controlled.

3.4
Key Characteristic (KC) owner
the person or function that defines the KCs and recognizes the reasons for the selection of the KCs. Typically, these responsibilities are held by internal/external customer design, quality, manufacturing, or maintenance engineering and are identified by a cross-functional team.

3.5
Key Characteristic (KC) process owner
the person or function that uses KC data to maintain and improve the process.

3.6
Process Control Document (PCD)
a written description of manufacturing/maintenance plan developed to control variation in KCs. It is a living document and is updated to reflect the addition/deletion of KCs.

3.7
Producer
an organization that performs any process affecting the manufacture or maintenance of the part/product.

3.8
Special cause
variation caused by a source that is not part of the constant system or process.

NOTE Also commonly referred to as 'assignable cause'.

4 General requirements

4.1 This clause defines general requirements which shall be met regardless of the variation management methodology applied.

NOTE Further detailed guidelines are provided in Annex A.

4.2 Variation management activities shall be performed on identified KCs and processes until they are in control and the required process capability has been established. Appropriate monitoring methodology should then be implemented to ensure continued performance.

4.3 The producer shall maintain appropriate documentation of KCs and manufacturing or maintenance process elements that influence variation in KCs as well as their control techniques and measurement methods. This documentation shall be developed when any of the following occurs:

a) Customer defines a CI or product/process KC.

b) Lower level or substitute KCs are required to control variation of higher level KCs.

c) Analysis performed as part of a process improvement activity to meet quality objectives required by 9100/9110 standard results in the identification of a KC or process.

NOTE PCD shown in Annex B in one acceptable method of documentation.

4.4 If Statistical Process Control (SPC) is chosen as the method of control for the KC, the following requirements shall be met:

a) Process capability shall be established for KCs. The process capability index (e.g., Cp and Cpk) shall be calculated only when the process is shown to be stable and in statistical control, using appropriate statistical methods and/or appropriate control charts.

b) The process shall be capable (i.e., with Cpk > 1.33) or as specified by the customer.

NOTE A KC is considered capable, if its Cpk meets or exceeds 1.33. Other comparable measures of process capability may be used. If the process does not meet capability requirements, the producer may have several options as described in this sub-clause.

c) When similar KCs from different products are combined on the same control chart (e.g., a part, product family, or process output control approach), the characteristics shall have similar variability and be traceable to the specific part or product.

d) When process capability is used to justify reduced frequency of inspection, the process capability (probability of nonconformance) shall be determined using recognized industry statistical methods.

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 conformance of products to specifications, or SPC methods with a process control plan; and audit records showing that the process is consistently practiced as defined (see Clause 4.3).

e) Processes that cease to be in control and/or capable and the product feature is under a reduced inspection plan, normal end-item inspection shall resume for acceptance of the product feature until the cause has been identified, corrected and process capability and control are re-established.

4.5 As applicable, other variation control methods (e.g., tooling, control of process KCs, standard processes, mistake proofing) shall be used to ensure process control and capability. Measurable evidence shall demonstrate that the controls are effective.

4.6 Focusing on KCs does not relieve the producer from meeting all drawing characteristics, specifications, and other customer requirements and/or invoked standards.

4.7 In some cases, it may be impossible or prohibitively expensive to meet the stability and capability requirements of this clause. These exceptions shall be documented by the producer and may require customer approval.

5 Process model

This clause describes a model that may be used in fulfilling the requirements of this standard and is presented for illustration and clarity.

The model consists of several stages, starting with the definition of product/process related KCs and/or identification of CIs, whose control is achieved through KCs variation management, and ending with the monitoring of product manufacturing or maintenance process performance. Further detailed guidance is provided in Annex A; other methods or processes may be employed to achieve compliance. The producer, in either case, shall show compliance with the requirements defined in Clause 4 has been achieved and the method by which compliance was obtained (see Figure 1).

6 Notes

6.1 A change bar (I) located in the left margin is for the convenience of the user in locating areas where technical revisions, not editorial changes, have been made to the previous issue of this document. An (R) symbol to the left of the document title indicates a complete revision of the document, including technical revisions. Change bars and (R) are not used in original publications, nor in documents that contain editorial changes only.