



SLOVENSKI STANDARD

SIST EN 9103:2008

01-junij-2008

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

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

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

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Ta slovenski standard je istoveten z: EN 9103:2005

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ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

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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 - Qualitätsmanagementsystems -
Management der Veränderung der Haupteigenschaften

This European Standard was approved by CEN on 28 October 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Foreword

This European Standard (EN 9103:2005) has been prepared by the European Association of Aerospace Manufacturers - Standardization (AECMA-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 AECMA, 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 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.

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.

In December 1998, the Aerospace Industry established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream.

This organization, with representation from Aerospace companies in Americas, Asia and Europe and sponsored by SAE, SJAC and AECMA has agreed to take responsibility for the technical contents of this standard.

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

Introduction

This Standard establishes variation management requirements for Key Characteristics. The Standard also specifies general requirements and provides a process to achieve those requirements.

The Standard requires a thorough assessment of the part production process with the primary goals being to control and minimize variation in characteristics being produced by this process.

Specifically, the Standard mandates:

- Understanding process elements that affect Key Characteristics.
- Disciplined determination of process Key Characteristics 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 Documentation that defines specific control of Key Characteristics and manufacturing process parameters.

This standard does not:

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

Although this Standard is focused on production and variation control of Key Characteristics, this process can also be used as a model for other characteristics, such as those that affect cost and delivery.

1 Scope

1.1 General

This Standard is primarily intended to apply to new parts, but can also be applied to parts currently in production. The Standard shall be applicable to all production processes that influence the variation of Key Characteristics.

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

1.2 Purpose

This Standard is designed to drive the improvement of manufacturing processes through adequate planning and effective management of Key Characteristic variation. The Key Characteristic focus is intended to improve confidence for part features whose variation has a significant influence on end-product form, fit, performance, service life and manufacturability.

1.3 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" must be able to show that their approach meets the intent of the requirements of this standard.
- Words "typical", "example", "for reference" or "e.g." indicate suggestions given for guidance only.
- "Notes" are used for additional clarifications.
- Words or phrases with specific meaning pertaining to this document are capitalized and defined in Clause 3, Terms and definitions.

2 Normative references

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

EN 9100:2003, *Aerospace series — Quality management systems — Requirements (based on ISO 9001:2000) and Quality systems — Model for quality assurance in design, development, production, installation and servicing (based on ISO 9001:1994).*

EN 9102:2004, *Aerospace series — Quality Systems — First article inspection.*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

key characteristic

KC

the features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability

[EN 9100:2003, definition]

- This definition is further explained as follows: **Key Characteristics 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.
- **Key Characteristics for a process** are those selected measurable parameters of a process whose control is essential to manage variation of part or system Key Characteristics.
- **Substitute Key Characteristics** may be identified when a Customer-defined Key Characteristic is not readily measurable within the production setting and other characteristics may need to be controlled to ensure conformance.

3.2

producer

an organization that performs any process affecting the manufacture of the part

3.3

customer

the organization which provides Part or System Key Characteristics 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 Key Characteristics.

3.4

key characteristic owner

key characteristic owner is the person or function who defines the Key Characteristics and recognizes the reasons for the selection of the Key Characteristic

Typically, these responsibilities are held by Internal or External Customer Design, Quality or Manufacturing Engineering, and should be identified by a cross-functional team.

3.5

key characteristic process owner

the Key Characteristic Process Owner is the person or function who uses Key Characteristic data to maintain and improve the process

3.6

process control document

PCD

a Process Control Document (PCD) is a written description of manufacturing plan developed to control variation in Key Characteristics

It is a living document and is updated to reflect the addition/deletion of Key Characteristics.

3.7

special cause

the term "special cause" in this standard can be substituted by "assignable cause"

These terms have their usual meanings relative to Statistical Process Control methodology.

4 Applicability

This Standard applies to assemblies and all levels of parts within an assembly, including castings and forgings, and to organizations that are responsible for producing the design characteristics of the product. 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 Key Characteristics conform to Customer requirements.

5 General requirements

5.1 Clause 5 provides the following general requirements which must be met regardless of the variation management methodology applied.

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

5.3 The Producer shall maintain appropriate documentation of Key Characteristics and manufacturing process elements that influence variation in Key Characteristics as well as their control techniques and measurement methods. This documentation shall be developed when any of the following occurs:

- a) Customer defines a Key Characteristic or a key process parameter.
- b) Lower level or Substitute Key Characteristics are required to control variation of higher level Key Characteristics.
- c) Analysis performed as part of a process improvement activity to meet quality objectives required by EN 9100 results in the identification of a key characteristic or process.

NOTE Process Control Document (PCD) shown in Annex B is one acceptable method of documentation.

5.4 If statistical process control is chosen as the method of control for the Key Characteristic, the following requirements must be met:

- a) Process capability shall be established for Key Characteristics. 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 sound statistical methods and/or appropriate control charts.
- b) The process shall be capable, with $Cpk > 1.33$, or as specified by the Customer.

NOTE A Key Characteristic is considered capable if its Cpk 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 section.

- c) When similar Key Characteristics from different products are combined on the same control chart (a part or product family, or process output control approach), the characteristics shall have similar variability and be traceable to the specific part or product.
- d) If process capability is used to justify reduced frequency of inspection, the process capability or equivalent fallout rate shall be calculated using industry standard statistical methods.
- 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.

5.5 Other variation control methods such as tooling, control of process settings, standard processes and mistake proofing may be used to ensure process stability and capability. However, measurable evidence must demonstrate that the controls are effective.

5.6 Focusing on Key Characteristics does not relieve the Producer from meeting all drawing characteristics, specifications and other customer requirements and/or invoked standards.

5.7 The Producer shall be responsible for flow-down of the requirements of this document to subcontractor(s) to the extent necessary to ensure compliance to the requirements of this standard.

5.8 Requirements of Clause 5. These exceptions must be documented by the Producer and may require customer approval.

6 Process model

Clause 6 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 Key Characteristics and ending with the monitoring of product manufacturing process performance. Other methods or processes may be employed to achieve compliance. The Producer in either case must show that compliance with the requirements in Clause 5 has been achieved and the method by which compliance was obtained. See Figure 1.

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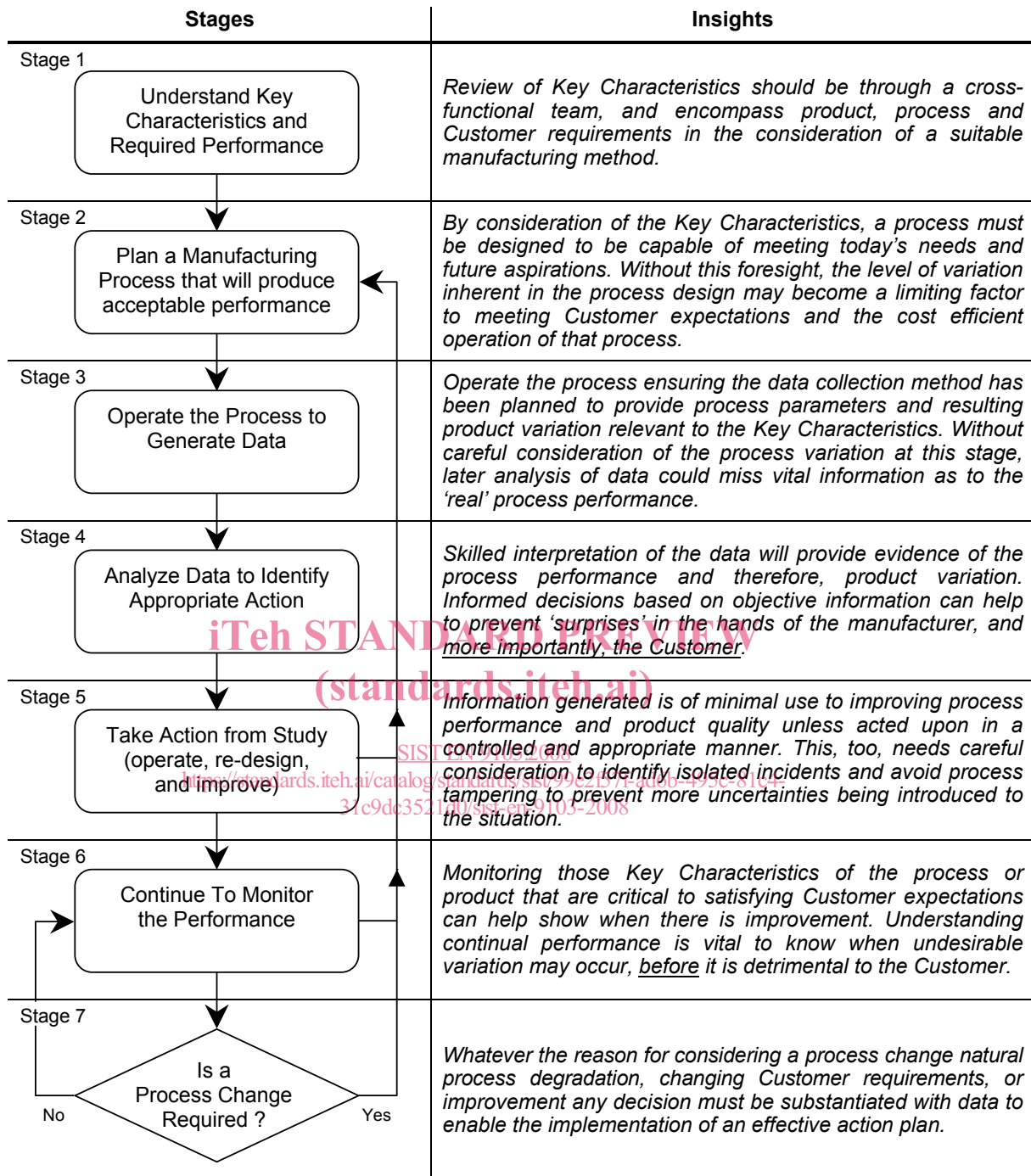


Figure 1 — Preferred Model for Key Characteristic Variation Management