SLOVENSKI STANDARD
oSIST prEN 9103:2022

01-december-2022

Aeronavtika - Sistemi vodenja kakovosti - Vodenje sprememb ključnih značilnosti

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 clés

Ta slovenski standard je istoveten z: **prEN 9103**

ICS:

03.100.70	Sistemi vodenja	Management systems
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

oSIST prEN 9103:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 9103

September 2022

ICS 03.100.70; 03.120.10; 49.020

Will supersede EN 9103:2014

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 clés

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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee ASD-STAN.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 9103:2022) 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 document 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 document is currently submitted to the CEN Enquiry.

This document will supersede EN 9103:2014.

Rationale

This document was revised to align with the latest revisions of the International Aerospace Quality Group (IAQG) standards (i.e. EN 9100, EN 9110, EN 9102, EN 9138, EN 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.

Introduction

To ensure customer satisfaction, 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 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 defence 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.

General

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

The document 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 document cannot be used as the basis for product acceptance and release. This document 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 document, 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 document, during the various phases of a program, when required by the customer or deemed appropriate by the organization (e.g. engineering, manufacturing).

Although this document is focused on variation control of KCs for manufacturing and maintenance activities, this document 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).

Application

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

— EN 9145 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.

— EN 9138 provides methods to ensure the minimum probability of conformity is achieved for each characteristic for which information is collected.

— EN 9102 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 EN 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 EN 9145 Phase 4 (Product and Process Validation), EN 9103 methods are used to verify the capability of the production processes prior to on-going production.

— By the end of EN 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 EN 9138 applies, that minimum value is designated the Initial Reliability Requirement (IRR).

— During EN 9145 Phase 5 (On-Going Production, Use, and Post-Delivery Service), the focus of EN 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.

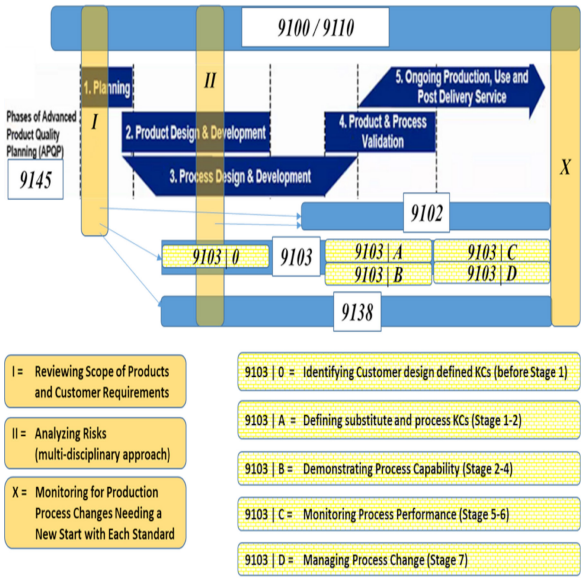

Figure 1 — Relationship for 9103 among other IAQG standards

1 Scope

1.1 General

This document 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). This document 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.

1.2 Purpose

This document 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 document does not constitute, nor imply acceptance of the resulting product. If variation management, under this document, is to be part of an acceptance decision, the requirements need to be specified in the applicable product acceptance plan or contract.

1.3 Convention

The following conventions are used in this document:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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. When a conflict between this document and the referenced standards exists, the requirements of this document shall take precedence. Further bibliographical information supporting EN 9103 implementation may be found in Annex A.

EN 9100,[1)] *Quality Management Systems — Requirements for Aviation, Space, and Defence Organizations*

EN 9101,[1)] *Quality Management Systems — Audit Requirements for Aviation, Space, and Defence Organisations*

ISO 3534-2,[2)] *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 9000,[2)] *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, the IAQG International Dictionary [3)], EN 9100 [4)], EN 9101 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp/ui
- IEC Electropedia: available at https://www.electropedia.org/

3.1
common cause
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 1 to entry: 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)
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 to entry: Design characteristics can be measured, inspected, tested, or verified to determine conformity to the design requirements.

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1) 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)].
2) Published by: ISO International Organization for Standardization http://www.iso.ch/.
3) Located on the IAQG website: https://iaqg.org/tools/dictionary/.
4) Particularly critical items (CIs) and special requirements.