SLOVENSKI STANDARD
SIST EN 9133:2018

01-september-2018

Nadomešča:
SIST EN 9133:2005

Aeronavtika - Sistemi vodenja kakovosti - Postopek za razvrščanje standardiziranih proizvodov v aeronavtiki

Aerospace series - Quality Management Systems - Qualification Procedure for Aerospace Standard Products

Luft- und Raumfahrt - Qualitätsmanagementsystem - Qualifikationsverfahren für genormte Teile der Luft- und Raumfahrt

Série aérospatiale - Systèmes de management de la qualité - Procédure de qualification pour pièces aérospatiales normalisées

Ta slovenski standard je istoveten z: **EN 9133:2018**

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

SIST EN 9133:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 03.100.70; 03.120.10; 49.020

Supersedes EN 9133:2004

English Version

Aerospace series - Quality Management Systems - Qualification Procedure for Aerospace Standard Products

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Luft- und Raumfahrt - Qualitätsmanagementsystem - Qualifikationsverfahren für genormte Teile der Luft- und Raumfahrt

This European Standard was approved by CEN on 18 September 2017.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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European foreword

This document (EN 9133:2018) 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 December 2018, and conflicting national standards shall be withdrawn at the latest by December 2018.

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 9133:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Rationale

This document has undergone full technical revision to reflect improvements introduced to the product qualification process and incorporate identified best practices since its initial release.

This document defines the process by which a manufacturer wishing to manufacture aviation, space, and defence standard products may obtain qualification approval from the controlling Certification Authority (CA). It defines the procedures to be followed by a manufacturer to request, carry out, obtain, and maintain certification approval by confirming the manufactured products meet the minimum technical and performance requirements defined by the product standard and controlling technical specifications.

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 complexity of resulting organizations' supply chains have 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. Furthermore, the aviation, space, and defence suppliers and processors, within the industry, 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 aviation, space, and defence companies in the Americas, Asia/Pacific, and Europe. This document defines the qualification of standard products and should result in improved quality and safety, and decreased cost, due to the standardization of this process.

1 Scope

1.1 General

This document defines a system for the qualification of standard products for aviation, space, and defenc applications. It defines the principles that shall be adhered to when carrying out product qualification; applied in conjunction with the rules and procedures of the CA. The system enables the CA to confirm compliance is achieved and maintained, in accordance with the requirements of its product definition and associated controlling technical specifications by an Original Component Manufacturer (OCM) of standard products.

This document requires an OCM that has been granted product qualification approval to ensure applicable approvals are maintained and renewed in accordance with the CA's quality system for that qualified product.

OCMs and OCM designated Value Added Distributors (VADs) requesting product qualification to this standard, shall as a prerequisite, maintain EN 9100 standard quality management system certification approval. This certification shall be visible in the Online Aerospace Supplier Information System (OASIS) database.

1.2 Application

The application of this document will be mandated either in the product standard or its controlling technical specifications. When invoked, the OCM wanting to produce aerospace standard products will need to gain qualification approval from an aerospace CA. The processes defined herein will be performed impartially for the benefit of the aerospace industry, by the CA, to ensure continued compliance of standard products to the requirements defined in their controlling technical specifications.

OCMs will need to ensure they allow sufficient lead-time to complete this process to gain product approval from the CA to support/satisfy their customer delivery requirements. Qualified products using this process shall not be supplied or used without qualification approval and a valid Product Qualification Certificate (PQC) being granted.

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.

EN 9100, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

EN 9102, *Aerospace series — Quality systems — First article inspection requirements*

EN 9103, *Aerospace series — Quality management systems — Variation management of key characteristics*

NOTE Equivalent versions (e.g. AS, EN, JISQ, SJAC, NBR) of the IAQG standards listed above are published internationally in each IAQG sector.

EN ISO 9000, *Quality management systems — Fundamentals and vocabulary*

EN ISO 9001, *Quality management systems — Requirements*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ASD-CERT Quality Manual (see www.asd-cert.org)

AC7101/1[1], *Nadcap Audit Criteria for Materials Testing Laboratories — General Requirements for all Laboratories*

AC7102[1], *Nadcap Audit Criteria for Heat Treating*

AC7108[1], *Nadcap Audit Criteria for Chemical Processing*

AC7114[1], *Nadcap Audit Criteria for Nondestructive Testing (NDT) Suppliers — Accreditation Program*

PD2000[1], *Governance and Administration of an Industry Managed Product Qualification Program*

PD2001[1], *Manufacturer Request for Product Approval and Qualification Process*

3 Terms and definitions

For the purpose of this document, the terms and definitions provided in EN ISO 9000 and the following apply. Furthermore, an acronym log for this standard is presented in Annex A.

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

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

3.1
analogy
act of granting product qualification certification approval based on testing that has been carried out on similar qualified product; where the new standard product's manufacturing method is substantially the same as the manufacturing method of the existing qualified product

3.2
Certification Authority
CA
authority that administers a certification system for qualification of standard products (e.g. ASD-CERT, SAE-PRI); acknowledged by the aviation, space, and defence industry Original Equipment Manufacturers (OEMs) and associated regulatory agencies [i.e. Federal Aviation Administration (FAA), European Aviation Safety Agency (EASA), or similar]

3.3
end user
organization purchasing aviation, space, and defence ualified standard products. Could be an OEM, OCM, and/or government agency purchasing standard products to be utilized within an assembly, part, or finished product

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1 Documents published by Performance Review Institute (PRI) and available from www.eAuditNet.com

3.4
First Article Inspection
FAI
planned, complete, independent, and documented inspection and verification process to ensure that prescribed production processes have produced an item conforming to engineering drawings, Digital Product Definition (DPD), planning, purchase order, engineering specifications, and/or other applicable design documents as defined by the EN 9102 standard

3.5
First Article Inspection Report
FAIR
forms and package of documentation for a part number, sub-assembly, or assembly, including associated FAI results as defined by the EN 9102 standard

3.6
grandfather qualified product status
act of an OCM requesting qualified product approval from a CA based on them having existing and current approval for the product standard listed on a Qualified Products List (QPL) with another OEM, government, or military organization

3.7
Mandated Body
MB
OEM who benefits from the qualification of standard products and use of qualified products; nominates the Mandated Body Representatives (MBRs)

3.8
Mandated Body Representative
MBR

individual accepted by the CA, based on their knowledge and experience as an industry Subject Matter Expert (SME), to act as agent on behalf of the CA; tasked with assessing if an OCM's products comply with applicable controlling product standards and technical specifications

3.9
Manufacturing Change Request
MCR
process employed by the qualified OCM to request a change to a manufacturing sealed route for qualified product from the CA

3.10
manufacturing sealed route
list of the manufacturing drawings, significant manufacturing operations, manufacturing flowchart, raw materials, components, subcontracted and/or VAD activities, and processes identified by name and controlling document number that are used to manufacture the product being qualified

3.11
Memorandum of Understanding
MoU
written agreement between two organizations to work together in support of a common goal or deliverable

3.12
Original Component Manufacturer
OCM
company or organization manufacturing standard products (see 3.23) requiring qualification approval from a CA

3.13
Original Equipment Manufacturer
OEM
manufacturer of an end user item, system, or subsystem [e.g. an airframe, power system (engine), auxiliary power unit]

3.14
Product Qualification Certificate
PQC
serialized document that certifies an OCM of standard product has been granted qualification approval by a CA, according to the relevant product standard and technical specifications. It defines the qualified product part numbers, applicable technical specifications, the approved OCM and applicable manufacturing site(s), period of approval, and the certificate renewal date (i.e. expiry date)

3.15
product qualification review
act of confirming compliance to an OCM's Qualification Test Program (QTP) for product being qualified to applicable product standards and technical specifications; activity overseen by either a MBR or carried out by an independent Nadcap approved test laboratory (e.g. AC7101/1) culminating in a Qualification Activity Report (QAR) being submitted to the CA for review and approval

3.16
product standard

standard defined and approved by consensus agreement of industry SMEs; issued by a Standards Development Organization (SDO)

3.17
Qualification Activity Report
QAR
report submitted by the MBR with the relevant supporting data and their recommendation to the CA (see Clause 7 and Annex B)

3.18
Qualification Test Program
QTP
program defined by the product manufacturer (i.e. OCM) or OCM designated VAD to confirm compliance of their standard product to the requirements of applicable product standards and associated technical specifications. Standard product qualification may be a combination of tests, analysis, or other supporting documentation or declarations of compliance

3.19
Qualification Test Report
QTR
report compiled by the OCM or OCM designated VAD that contains the associated test results in accordance with the QTP and EN 9102 standard FAIR requirements

3.20
qualified product
aerospace standard product that has been confirmed by witness assessment and approval by a CA as complying with applicable key characteristics and defined product standard and technical specification(s) requirements

3.21
Qualified Products List
QPL
directory of qualified products and their OCMs (e.g. ASD-Cert qualified products directory is available at www.asd-cert.org, PRI qualified products directory is available at www.eAuditNet.com) and OCMs granted approval for a specific product part number designation, including identification of applicable manufacturing facilities

3.22
quality manual or program document
document that defines the management system, organization management structure, and processes to be administered; enables an OCM to obtain standard product qualification approval, be issued a PQC, and listed in a QPL (e.g. ASD-CERT Quality Manual, PD2000, PD2001)

3.23
standard product
product (see 3.16) controlled by product standard definition produced by a SDO (see 3.24). The term can apply to hardware (e.g. fasteners, connectors, fittings), materials, coatings, sealants, and products that can have their key characteristics assessed for compliance by product qualification to this standard. This may also apply to products referred to as standard catalogue items, as defined by the EN 9102 standard

3.24
Standards Development Organization
SDO
recognized national or international organization commissioned to develop standards and technical specifications for aerospace applications through the input of industry SMEs to achieve consensus agreement for the product standards developed

3.25
Subject Matter Expert
SME
individual who has been accepted by industry peers as having gained expert knowledge of specific products/subjects obtained through academic study, continued training, and/or product standard development experience for a SDO

3.26
technical specification
specification identified on the product standard that defines the procedures, technical requirements, manufacturing process(es), and testing and inspection requirements to be performed on a product manufactured by an OCM. It defines the product's key attributes that must be achieved by testing and inspection at the initial product qualification review and for each production batch of products manufactured

3.27
Value Added Distributor
VAD
manufacturer or distributor designated and monitored by the qualified OCM to complete the final assembly of the constituent components of a qualified product and act as a distributor of the finished product assembled on behalf of the qualified OCM

4 Qualification process

4.1 The qualification process shall follow the stages defined in the application flow chart (see Figure 1).

4.2 An OCM seeking to obtain approval to manufacture a qualified product shall apply to the CA, using the appropriate process(es) defined in the CA's quality manual or program document. The following data/information shall be provided:

a) description of the product to be qualified; identifying the applicable technical specifications and the relevant qualification standard to be used;

b) an overview of the company (e.g. organization, shareholders and parent companies, products manufactured, manpower, facilities);

c) a list of quality approvals and/or qualifications already granted to the OCM, including additional supporting information on similar qualified products;

d) a copy of the OCM's EN 9100 quality management system certificate (registered on the OASIS database) and any other applicable certifications/accreditations (e.g. Nadcap accreditations), if applicable to the product manufacturing process and/or relevant to the request being submitted. Any external subcontractors (e.g. machining, heat treatment, or plating suppliers) identified shall have EN 9100 Quality Management System Certification and the applicable Nadcap accreditations for the operations being conducted;

e) details of product manufacturing route, including details of all special processes and inspection techniques to be used (see 4.2 d)).

4.3 On receipt of a request from an OCM, the CA shall identify a MBR (see Clause 5) to act on their behalf to carry out the product qualification review, which can include the need to witness product testing in accordance with the applicable product standard and technical specification requirements. The approved individual shall either be an employee of an OEM or an individual employed by an organization that has a Memorandum of Understanding (MOU) with the CA for carrying out product qualifications.

4.4 The information provided by the OCM shall be forwarded by the CA to the MBR selected to carry out the product qualification review in accordance with Clause 6.

4.5 The manufacturing sealed route shall be provided by the OCM and sealed (i.e. frozen) by the MBR (see 6.1). The EN 9103 standard may be used at the discretion of the MBR. The key characteristics of the standard product and the associated technical specifications shall be identified and may be used to assess the competency and capability of the OCM identified to produce the qualified product.

4.6 The OCM or OCM designated VAD shall conduct a FAI, if applicable, for the product to be qualified in accordance with the EN 9102 standard requirements.

4.7 An OCM that wishes to add a designated VAD to their PQC shall submit a separate qualification request, supplying details (see 4.2 and 4.5) for each VAD they want to incorporate into their