



SLOVENSKI STANDARD

SIST EN 9115:2018

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Nadomešča:

SIST EN 9115:2013

Sistemi vodenja kakovosti - Zahteve za organizacije za zračni promet, astronautiko in obrambo - Dobavljivost programske opreme (dopolnilo k EN 9100)

Quality Management Systems - Requirements for Aviation, Space and Defense Organizations - Deliverable Software (Supplement to EN 9100)

Qualitätsmanagementsysteme - Anforderungen an Organisationen der Luftfahrt, Raumfahrt und Verteidigung - Mittelieferte Software (Ergänzung zu EN 9100)

Systèmes de management de la Qualité - Exigences pour les Organisations de l'Aéronautique, l'Espace et la Défense - Logiciel livrable (Supplément à l'EN 9100)

Ta slovenski standard je istoveten z: EN 9115:2018

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
95.020	Vojaštvo na splošno	Military in general

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EUROPEAN STANDARD

EN 9115

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2018

ICS 03.100.70; 03.120.10; 35.080; 49.020

Supersedes EN 9115:2013

English Version

Quality Management Systems - Requirements for Aviation, Space and Defense Organizations - Deliverable Software (Supplement to EN 9100)

Systèmes de management de la Qualité - Exigences
pour les Organisations de l'Aéronautique, l'Espace et la
Défense - Logiciel livrable (Supplément à l'EN 9100)

Qualitätsmanagementsysteme - Anforderungen an
Organisationen der Luftfahrt, Raumfahrt und
Verteidigung - Mitgelieferte Software (Ergänzung zu
EN 9100)

This European Standard was approved by CEN on 28 March 2018.

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 9115:2018) 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 January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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

This document supersedes EN 9115:2013.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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EN 9115:2018 (E)**Rationale**

This European standard supersedes the initial release of prEN 9115 published in April 2010. This European standard has been revised to incorporate the new clause structure and content of EN ISO 9001:2015. In addition, industry requirements, definitions, and notes have been revised in response to EN ISO 9001:2015 and EN 9100:2016 revisions and stakeholder needs.

This is the second revision of EN 9115 which is an international supplement to EN 9100 providing clarification of the corresponding EN 9100 requirements, as necessary, for deliverable software. In some cases, where clarification is needed, it was necessary due to the complexity of software to decompose “shall” statements in EN 9100 into more granular requirements. Where no software clarification is required of the EN 9100 requirements, the following phrase is presented: “The requirements of EN 9100 apply. No clarification required for software.”

NOTE This document must be used in conjunction with EN 9100:2016; references throughout the text to EN 9100 are understood to mean EN 9100:2016.

Foreword

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This document standardizes, to the greatest extent possible, the software quality management system requirements for the aviation, space, and defence industry. This was accomplished through the harmonization of quality management system requirements from international aviation, space, and defence software standards and other applicable documents and good practice. The establishment of common requirements for use at all levels of the supply-chain by organizations around the world should result in improved quality, schedule, and cost performance by the reduction or elimination of organization unique requirements and wider application of good practice.

Intended Application

The requirements of EN 9100 apply with the following clarification for software.

Organizations whose products are deliverable software or contain deliverable software should use the supplemental EN 9115 standard when planning and evaluating the software design, development, release, procurement, and management activities of the organization. The EN 9115 standard provides guidance to the requirements of EN 9100 when it is desired to add “deliverable software” to the organization’s EN 9100-registration certificate, and a greater depth of specificity and granularity to the requirements for assuring that the objectives of EN 9100 will be met for deliverable software.

NOTE This document is independent of the life cycle models (e.g., waterfall, spiral, agile, evolutionary, incremental) or methodology (e.g., objected oriented design, unified modelling language).

0 Introduction

0.1 General

The requirements of EN 9100 apply. No clarification required for software.

0.2 Quality management principles

The requirements of EN 9100 apply. No clarification required for software.

0.3 Process approach

The requirements of EN 9100 apply. No clarification required for software.

0.3.1 General

The requirements of EN 9100 apply. No clarification required for software.

0.3.2 Plan-do-check-act cycle

The requirements of EN 9100 apply. No clarification required for software.

0.3.3 Risk-based thinking

The requirements of EN 9100 apply. No clarification required for software.

0.4 Relationship with other management system standards

The requirements of EN 9100 apply. No clarification required for software.

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EN 9115:2018 (E)**1 Scope**

The requirements of EN 9100 apply with the following clarification for software.

This European standard supplements the EN 9100 standard requirements for deliverable software and contains quality management system requirements for organizations that design, develop, and/or produce deliverable software and services for the aviation, space, and defence industry. This includes, as required, support software that is used in the development and maintenance of deliverable software and services. The deliverable software may be stand-alone, embedded, mobile application, or loadable into a target computer

This deliverable software may also be part of services (e.g., cloud environment, web hosted solutions or platforms).

Where the use of Hardware Description Language (HDL) or high order language is utilized as the design source of electronic hardware [e.g., Application Specific Integrated Circuit (ASIC), Programmable Logic Device (PLD)]; the organization and customer, and/or supplier shall agree on the extent of applicability of this supplement.

NOTE For airborne electronic hardware guidance, see RTCA/DO-254 or EUROCAE ED-80. For operations requirements, see EN 9100, clause 8.

Where Commercial-Off-The-Shelf (COTS) or non-developmental software is integrated into a deliverable product, the organization and customer shall agree on the extent of applicability of this supplement.

For the purposes of this document, the terms “product” and “software product” are considered synonymous.

For the purposes of this document, the term “services” may be considered a product.

2 Normative references

The requirements of EN 9100 apply with the following clarification for software.

EN 9100:2016, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

NOTE Documents referenced in this European standard, other than the normative references (i.e., EN ISO 9000, EN ISO 9001, EN 9100), are listed in the supporting bibliographies (see Annex A and Annex B). For undated references, the latest edition of the referenced document (including any amendments) applies. The referenced documents are “informative” references; the requirements of these referenced documents do not add any additional requirements to this European standard.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 9100 and EN ISO 9000 apply. The following terms and definitions are included to support the understanding of this document.

3.1 baseline

approved, recorded configuration of one or more configuration items that thereafter serves as the basis for further development, and is changed only through change control documented information [see RTCA/DO-178 or EUROCAE ED-12]

3.2**Commercial-Off-The-Shelf (COTS) Software**

commercially available applications sold by vendors through public catalogue listings. COTS software is not intended to be customized or enhanced. Contract-negotiated software developed for a specific application is not COTS software [see RTCA/DO-178 or EUROCAE ED-12]

Note 1 to entry: COTS software is a type of non-developmental software.

3.3**configuration item**

one or more hardware/software entities treated as a unit for configuration management purposes or software life cycle data treated as a unit for configuration management purposes

[SOURCE: RTCA/DO-178 or EUROCAE ED-12, modified]

3.4**critical items**

definition in EN 9100, 3.2, applies with the following clarification for software

Critical items in software are those characteristics, requirements, or attributes that have been determined to be most important to achieve product realization (e.g., safety, maintainability, testability, usability, performance). For example, in the case of an aircraft's flight control system software, the response time could be elevated to a critical item to ensure overall performance characteristics are met; or if a project has customer specific testability requirements, cyclomatic complexity may become a critical item.

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3.5**Cyclic Redundancy Check**

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CRC

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type of function that takes a data stream of any length as an input and produces a value of a certain space (commonly a 32-bit integer) as an output. A CRC can be used to detect alteration of data during transmission or storage

3.6**digital signature**

digital signature scheme

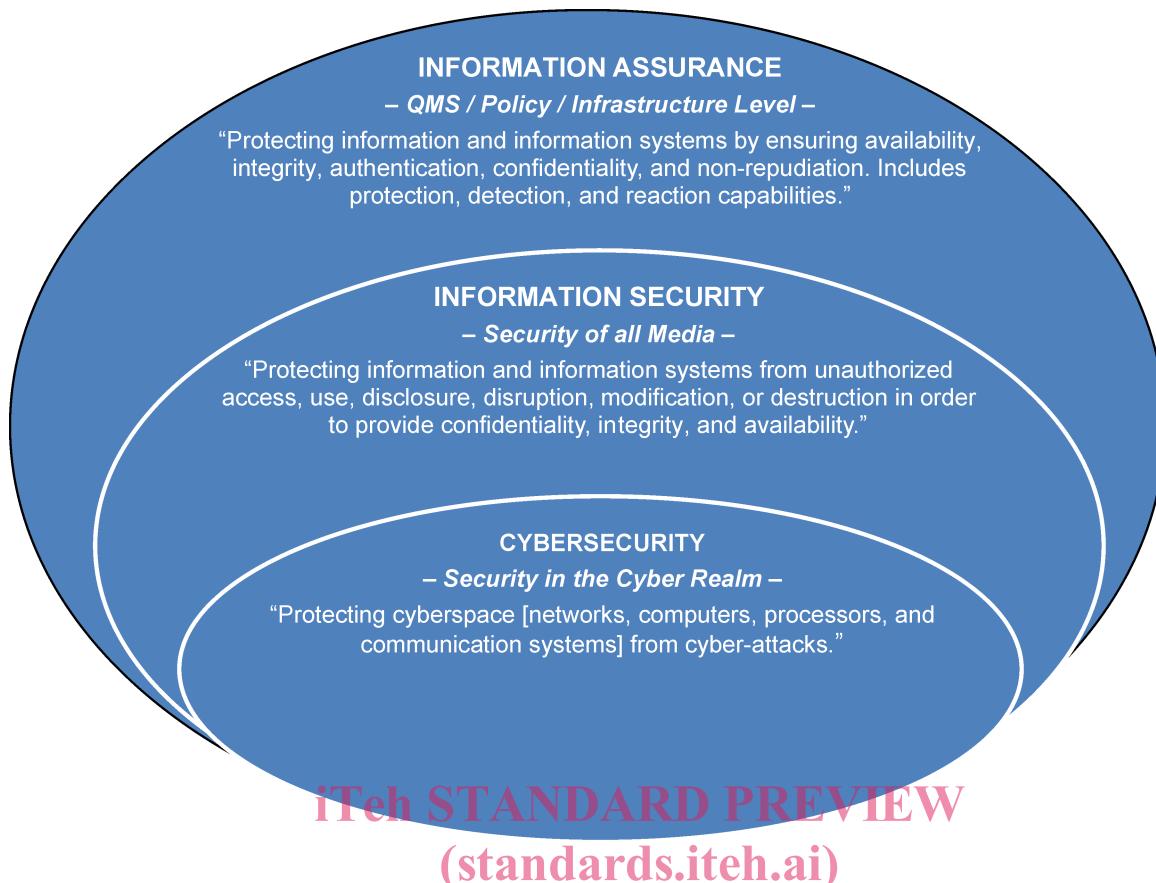
type of asymmetric cryptography used to express compliance with the security properties of a handwritten signature on paper

3.7**Information Assurance****IA**

set of activities needed to protect information and information systems by ensuring availability, integrity, authentication, confidentiality, and non-repudiation including protection, detection, and reaction capabilities

This includes activities conducted to reduce vulnerability of operational networks, Information Technology (IT), and computing equipment. Activities may include development of innovative and cost-effective ways to mitigate those vulnerabilities. IA may include actions to provide assured access, and transparent identification and authentication across the network or within systems of systems.

See Figure 1 for added clarity of related terms.



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Figure 1 — Relationship of information assurance, information security and cybersecurity

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References:

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- Committee on National Security Systems National Information Assurance Glossary, CNSSI Instruction No. 4009 (26th April 2010)
- ISO 27001:2013, *Information technology — Security techniques — Information security management systems — Requirements*
- ISO 27002:2013, *Information technology — Security techniques — Code of practice for information security controls*
- ISO 27034-1:2011, *Information technology — Security techniques — Application security — Part 1: Overview and concepts*

3.8

interested parties

party having a right, share, or claim in a system or in its possession of characteristics that meet that party's needs and expectations [see ISO/IEC 12207]

Note 1 to entry: Interested parties include, but are not limited to customers, suppliers, regulatory bodies, and functional organizations or groups needed to achieve product quality.

3.9**key characteristic**

definition in EN 9100, 3.3 applies with the following clarification for software

Key characteristics in software are those measurable attributes where variability can be measured by the project and can, if left unchecked, adversely impact the project or product in areas (e.g., memory utilization, response time, functionality, reliability, usability, efficiency, maintainability, portability).

3.10**monitoring**

act of witnessing or inspecting selected instances of test, inspections, or other activities, or documented information of those activities, to assure that the activity is under control and that the reported results are representative of the expected results. Such activities could be performed and used as evidence for formal test verification to support conformity, certification, and customer acceptance

Monitoring is usually associated with activities done over an extended period of time where 100 % witnessing is considered impractical or unnecessary. Monitoring permits authentication that the claimed activity was performed as planned [see RTCA/DO-178 or EUROCAE ED-12].

3.11**non-developmental software**

deliverable software that is not developed under the contract, but is provided by the organization, customer, or a third party [e.g., reused software, customer furnished software, COTS software, Government off-the Shelf (GOTS) software, open source software]

3.12**phase**

collection of processes, activities, tasks, and outcomes within the software life cycle [see IEEE 24765]

3.13**release**

particular version of a configuration item that is made available for a specific purpose (e.g., test release)

[SOURCE: ISO/IEC 12207]

3.14**reliability**

probability of failure-free operation of a computer program in a specified environment for a specified time [based on IEEE 982.1]

Note 1 to entry: Software reliability requirements should consider the level and manner of fault and failure detection, isolation, fault tolerance, and recovery expected to be fulfilled by the software.