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

EESTI STANDARDIKESKUS EVS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA   NATIONAL FOREWORD

See Eesti standard EVS-EN 9115:2018 sisaldab Euroopa standardi EN 9115:2018 ingliskeelset teksti.	This Estonian standard EVS-EN 9115:2018 consists of the English text of the European standard EN 9115:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.07.2018.	Date of Availability of the European standard is 11.07.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN 9115

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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.

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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

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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.

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

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.

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]