Quality Management Systems - Requirements for Aviation, Space and Defence Organizations - Deliverable ant is a provide of the second **Software (Supplement to EN 9100)**



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

	This Estonian standard EVS-EN 9115:2013 consists of the English text of the European standard EN
teksti.	9115:2013.
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.
,	Date of Availability of the European standard is 09.01.2013.
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.

ICS 03.120.10, 49.020

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega: Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation: Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD NORME EUROPÉENNE

EN 9115

EUROPÄISCHE NORM

January 2013

ICS 03.120.10; 49.020

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 18 June 2011.

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



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

		age
Forew	ord	4
0	Introduction	
0 0.1	General	
0. i 0.2	Process approach	
QUALI	TY MANAGEMENT SYSTEMS — REQUIREMENTS	
1	Scope	6
1.1	General	
1.2	Application	6
2	Normative references	.
3	Terms and definitions	
4	Quality management system	
4.1	General requirements	
4.2	Documentation requirements	
4.2.1	General	
4.2.2	Quality manual	
4.2.3 4.2.4	Control of documents Control of records	
4.2.4		
5	Management responsibility	
5.1	Management commitment	
5.2	Customer focus	
5.3	Quality policy	
5.4	Planning	
5.4.1	Quality objectives	
5.4.2	Quality management system planning	
5.5	Responsibility, authority and communication	
5.5.1	Responsibility and authority	
5.5.2	Management representative	
5.5.3 5.6	Internal communication	
5.6 5.6.1	General	
5.6.2	Review input	
ნ.ნ.∠ 5.6.3	Review output	
3.6.3		
6	Resource management	
6.1	Provision of resources	
6.2	Human resources	
6.2.1	General	
6.2.2	Competence, training and awareness	
6.3	Infrastructure	
6.4	Work environment	
7	Product realization	. 13
7.1	Planning of product realization	. 13
7.1.1	Project management	
7.1.2	Risk management	
7.1.3	Configuration management	
7.1.4	Control of work transfers	
7.2	Customer-related processes	. 16
721	Determination of requirements related to the product	16

7.2.2	Review of requirements related to the product	
7.2.3	Customer communication	
7.3	Design and development	
7.3.1	Design and development planning	17
7.3.2	Design and development inputs	17
7.3.3	Design and development outputs	17
7.3.4	Design and development review	17
7.3.5	Design and development verification	
7.3.6	Design and development validation	
7.3.6.1		
7.3.6.2	Design and development verification and validation documentation	18
7.3.7	Control of design and development changes	18
7.4	Purchasing	
7.4.1	Purchasing process	
7.4.2	Purchasing information	
7.4.3	Verification of purchased product	19
7.5	Production and service provision	
7.5.1	Control of production and service provision	19
7.5.1.1	Production process verification	19
	Control of production process changes	
7.5.1.3	Control of production equipment, tools and software programs	20
7.5.1.4	Post-delivery support	20
7.5.2	Validation of processes for production and service provision	20
7.5.3	Identification and traceability	20
7.5.4	Customer property	20
7.5.5	Preservation of product	
7.6	Control of monitoring and measuring equipment	21
8	Measurement, analysis and improvement	21
8.1	General	
8.2	Monitoring and measurement	21
8.2.1	Customer satisfaction	
8.2.2	Internal audit	
8.2.3	Monitoring and measurement of processes	
8.2.4	Monitoring and measurement of product	
8.3	Control of nonconforming product	
8.4	Analysis of data	
8.5	Improvement	
8.5.1	Continual improvement	
8.5.2	Corrective action	
8.5.3	Preventive action	
Riblion	uranhy.	23

Foreword

This document (EN 9115:2013) 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 July 2013, and conflicting national standards shall be withdrawn at the latest by July 2013.

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.

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

This document standardizes, to the greatest extent possible, the software quality management system requirements for the aviation, space, and defense industry. This was accomplished through the harmonization of quality management system requirements from international aviation, space, and defense software standards and other applicable documents. 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.

SUMMARY/RATIONALE

The 9115 document supersedes AS9006, "Deliverable Aerospace Software Supplement for AS9100A, Quality Management Systems — Aerospace — Requirements for Software", published in March 2003. The AS9006 standard was published as an Americas Aerospace Quality Group (AAQG) sector specific document.

This is the initial release of 9115, which is an international supplement to 9100 providing clarification of the corresponding 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 9100 into more granular requirements. Where no software clarification is required of the 9100 requirements, the following phrase will be presented: "The requirements of 9100 apply. No clarification required for software."

201, 1,2009. NOTE This document must be used in conjunction with EN 9100: references throughout the text to EN 9100 are understood to mean EN 9100:2009.

0 Introduction

0.1 General

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

0.2 Process approach

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

QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS

1 Scope

1.1 General

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

This document 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 for the aviation, space, and defense industry. This includes, as required, support software that is used in the development and maintenance of deliverable software. The deliverable software may be stand-alone, embedded, or loadable into a target computer.

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 shall agree on the extent of applicability of this supplement.

NOTE 1 For airborne electronic hardware guidance, see RTCA/DO-254 or EUROCAE ED-80; and for product realization requirements, see EN 9100.

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.

NOTE 2 This document is independent of the life cycle models (e.g., waterfall, spiral, evolutionary, incremental) or methodology (e.g., objected oriented design, unified modeling language, agile).

1.2 Application

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

Exclusions to requirements in Clause 7 should only be considered after analysis of software attributes (e.g., size, safety, security, complexity, criticality, risk).

2 Normative references

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

NOTE 1 The requirements of EN 9100 apply with the following clarification for software.

EN 9100:2009, Quality Management Systems — Requirements for Aviation, Space and Defence Organizations

NOTE 2 Documents referenced in this document, other than the normative references (i.e., 9100, ISO 9000) are listed in the Bibliography. 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 standard.

3 Terms and definitions

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

3.1

baseline

the approved, recorded configuration of one or more configuration items, that thereafter serves as the basis for further development, and that is changed only through change control procedures

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

3.2

Commercial-Off-The-Shelf (COTS) software

commercially available applications sold by vendors through public catalog listings. COTS software is not intended to be customized or enhanced. Contract-negotiated software developed for a specific application is not COTS software.

[SOURCE: RTCA/DO-178, 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: based on RTCA/DO-178, EUROCAE ED-12]

3.4

critical items

the definition in EN 9100, Clause 3.3, 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). Critical items should be adequately managed and appropriate action taken to ensure visibility throughout the product life cycle. For example, in a flight control system software response time can be elevated to a critical item to ensure performance characteristics are met. Furthermore, if the project has specific testability requirements, cyclomatic complexity may become a critical item.