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

I.S. EN 9115:2013

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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 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.

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Contents

Page

Foreword.....	4
0 Introduction	6
0.1 General.....	6
0.2 Process approach.....	6
QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS.....	6
1 Scope	6
1.1 General.....	6
1.2 Application	6
2 Normative references	7
3 Terms and definitions	7
4 Quality management system	10
4.1 General requirements.....	10
4.2 Documentation requirements.....	10
4.2.1 General.....	10
4.2.2 Quality manual	10
4.2.3 Control of documents	11
4.2.4 Control of records.....	11
5 Management responsibility	11
5.1 Management commitment	11
5.2 Customer focus.....	11
5.3 Quality policy	11
5.4 Planning.....	11
5.4.1 Quality objectives	11
5.4.2 Quality management system planning.....	11
5.5 Responsibility, authority and communication.....	11
5.5.1 Responsibility and authority	11
5.5.2 Management representative	11
5.5.3 Internal communication	11
5.6 Management review.....	12
5.6.1 General.....	12
5.6.2 Review input.....	12
5.6.3 Review output	12
6 Resource management	12
6.1 Provision of resources	12
6.2 Human resources.....	12
6.2.1 General.....	12
6.2.2 Competence, training and awareness	12
6.3 Infrastructure.....	12
6.4 Work environment	13
7 Product realization.....	13
7.1 Planning of product realization	13
7.1.1 Project management	13
7.1.2 Risk management	14
7.1.3 Configuration management	14
7.1.4 Control of work transfers.....	16
7.2 Customer-related processes	16
7.2.1 Determination of requirements related to the product	16

7.2.2	Review of requirements related to the product.....	16
7.2.3	Customer communication	17
7.3	Design and development.....	17
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.....	18
7.3.6	Design and development validation	18
7.3.6.1	Design and development verification and validation testing	18
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	19
7.4.1	Purchasing process	19
7.4.2	Purchasing information	19
7.4.3	Verification of purchased product.....	19
7.5	Production and service provision	19
7.5.1	Control of production and service provision	19
7.5.1.1	Production process verification	19
7.5.1.2	Control of production process changes	20
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.....	20
7.6	Control of monitoring and measuring equipment	21
8	Measurement, analysis and improvement.....	21
8.1	General	21
8.2	Monitoring and measurement.....	21
8.2.1	Customer satisfaction.....	21
8.2.2	Internal audit	21
8.2.3	Monitoring and measurement of processes.....	21
8.2.4	Monitoring and measurement of product	21
8.3	Control of nonconforming product	22
8.4	Analysis of data	22
8.5	Improvement.....	22
8.5.1	Continual improvement	22
8.5.2	Corrective action	22
8.5.3	Preventive action.....	22
	Bibliography.....	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.”

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.

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