

BS EN 9115:2013



BSI Standards Publication

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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee ACE/1, International and European Aerospace Policy and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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© The British Standards Institution 2013.
Published by BSI Standards Limited 2013

ISBN 978 0 580 67509 6

ICS 03.120.10; 49.020

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2013.

Amendments issued since publication

Date	Text affected
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EUROPEAN STANDARD

EN 9115

NORME EUROPÉENNE

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.

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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of an identical text or by endorsement, at the latest by July 2013, and conflicting national standards shall be withdrawn at the latest by July 2013.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.

3.5
cyclic redundancy check (CRC)

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

3.6
digital signature

a type of asymmetric cryptography used to express compliance with the security properties of a handwritten signature on paper, also referred to as a digital signature scheme

3.7
key characteristic

the definition in EN 9100, Clause 3.4, 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., schedule, cost, maintainability, testability, reliability, portability). Examples of key characteristics include defect severity, complexity factors, nested menus, memory, timing, response time, and throughput targets.

3.8
Monitoring

the act of witnessing or inspecting selected instances of test, inspections, or other activities, or records of those activities, to assure that the activity is under control and that the reported results are representative of the expected results

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.

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

3.9
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, open source software)

3.10
phase

a collection of processes, activities, tasks, and outcomes within the software life cycle

3.11
release

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

[SOURCE: ISO/IEC 12207]

3.12
reliability

the probability of failure-free operation of a computer program in a specified environment for a specified time

[SOURCE: based on IEEE-STD-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.

3.13
risk

the definition in EN 9100 (see 3.1) applies. No clarification required for software.

3.14
robustness

the extent to which software can continue to operate correctly despite invalid inputs

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

Note 1 to entry: Robustness, in the software context, means that the organization has utilized techniques (e.g., exception handling, redundancy, related verification techniques).

3.15
secure hash algorithm

cryptographic functions that compute a fixed-length digital representation, known as a message digest, of an input data sequence of any length

3.16
software

computer programs, associated documentation, and data pertaining to the operation of a computer system

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

Note 1 to entry: The executable programs and data that are embedded in hardware devices are considered to be included in this definition (i.e., firmware).

Note 2 to entry: Firmware is the combination of a hardware memory device loaded with computer instructions and/or digital data that reside as read-only software on a device that a computing system can read. The software cannot typically be readily modified under program control.

3.17
software life cycle

the period of time that begins with the decision to produce or modify software and ends when the software product support is no longer required. The software life cycle contains phases.

Note 1 to entry: The software life cycle typically includes a concept phase, requirements phase, design phase, implementation phase, test phase, installation and checkout phase, operation and maintenance phase, and sometimes, retirement phase

[SOURCE: IEEE-STD-610.12]

3.18
software product

the set of computer programs and associated documentation and data intended for, or required by, a customer; or any intended output resulting from the product realization process

Note 1 to entry: A software product may be designated for delivery, an integral part of another software or hardware product, or used in the development process.

3.19
special requirements

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

Examples of special requirements that may introduce high risk for software include: the introduction of a new compiler, new advanced modeling technique, qualification of tools, novel test equipment capabilities, introduction of a new type of interface, or novel customer technical requirements. These requirements are included in the risk management process.

**3.20
stakeholder**

a party having a right, share, or claim in a system or in its possession of characteristics that meet that party's needs and expectations

[SOURCE: ISO/IEC 15288]

Note 1 to entry: Stakeholders include, but are not limited to customers, suppliers, regulatory bodies, and functional organizations or groups involved in product realization.

**3.21
support software**

software that aids in the development or maintenance of other software (e.g., compilers, loaders, other utilities)

[SOURCE: IEEE-STD-610.12]

**3.22
validation**

confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled

[SOURCE: ISO/IEC 12207]

Note 1 to entry: Validation ensures that "you built the right item".

**3.23
verification**

confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

[SOURCE: ISO/IEC 12207]

Note 1 to entry: Verification ensures that "you built the item right".

4 Quality management system

4.1 General requirements

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

4.2 Documentation requirements

4.2.1 General

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

4.2.2 Quality manual

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

The quality manual shall address quality management system requirements for software via inclusion or reference.

4.2.3 Control of documents

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

4.2.4 Control of records

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

Where records are held on electronic media, consideration of the retention times and accessibility of the records should take into account the rate of degradation of the electronic media and the availability of the devices and software needed to access the records.

5 Management responsibility

5.1 Management commitment

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

5.2 Customer focus

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

5.3 Quality policy

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

5.4 Planning

5.4.1 Quality objectives

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

5.4.2 Quality management system planning

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

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

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

5.5.2 Management representative

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

5.5.3 Internal communication

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

5.6 Management review

5.6.1 General

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

5.6.2 Review input

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

5.6.3 Review output

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

6 Resource management

6.1 Provision of resources

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

6.2 Human resources

6.2.1 General

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

6.2.2 Competence, training and awareness

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

6.3 Infrastructure

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

The organization shall determine, provide, and maintain an infrastructure, as appropriate, to support the software life cycle.

Organization infrastructure includes, as applicable:

- a) software development tools and utilities, including host computer and support software;
- b) software verification tools and utilities, including test equipment and test software;
- c) equipment, tools, and utilities for archiving and storage, disaster recovery, protection, replication, software loading, transmittal, record retention, software quality, and configuration management;
- d) integrity verification tools and utilities (e.g., virus protection/checking, digital signatures, secure hash algorithms, CRC);
- e) equipment and software needed to meet retention requirements; and
- f) security for software environments against attacks (e.g., malicious code, enumeration, fingerprints, worms, viruses, backdoors, spyware).

6.4 Work environment

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

Consideration should be given to ensure the software environment is managed for proper configuration updates, as appropriate, including software and hardware updates.

7 Product realization

7.1 Planning of product realization

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

Software planning shall address software related activities from project planning through product delivery and maintenance, including the following, as appropriate:

- a) quality objectives and requirements expressed in measurable terms, including critical items and key characteristics;
- b) the software life cycle;
- c) identification, qualification, selection, and management of suppliers;
- d) evaluation, qualification, verification, and approval of non-developmental and support software;
- e) required infrastructure items (see 6.3);
- f) monitoring, evaluation, and audit of software and related activities;
- g) the level of criticality for software, as based upon the contribution of software to potential failure conditions;
- h) safety and security requirements for the product and data;
- i) standards (e.g., design and coding standards), rules, practices, conventions, techniques, and methodologies for development and test;
- j) tools, templates, and work aids;
- k) roles and responsibilities between stakeholders;
- l) installation and support of the product;
- m) product verification, validation, acceptance, and delivery; and
- n) copyright, licensing concerns, Intellectual Property Rights (IPR), and export controls.

7.1.1 Project management

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

In addition to the normal project management measures, software projects should consider other progress indicators (e.g., requirements, lines of code, test progress), problem report aging, or open problem reports near software development completion.

7.1.2 Risk management

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

Risk management shall address special requirements (see 3.19) for software.

NOTE Actions to mitigate the risk may include additional training for use of new tools or equipment, or interface prototyping.

7.1.3 Configuration management

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

The organization shall establish, implement, and maintain a configuration management process for software products as follows.

7.1.3.1 Configuration management planning

Software configuration management planning shall include:

- a) roles and responsibilities for configuration management;
- b) configuration management activities, schedules, and records;
- c) criteria and guidance for verification and validation of changes;
- d) configuration management tools, techniques, and methods to be used;
- e) the criteria for when configuration items are brought under formal change control;
- f) the management and control of non-developmental software and support software, as appropriate;
- g) the criteria for when non-developmental software is to be brought under the product's configuration control;
- h) processes for preservation of product in accordance with Clause 7.5.5;
- i) the criteria and guidance for the application of a localized temporary change, and criteria for when a new release is required; and
- j) period of retention, retirement, obsolescence, and destruction of software products.

Planning shall also ensure the following provisions are addressed in the replication processes:

- k) identification of the master and copies, including format and version;
- l) type of media for software products and its associated labeling;
- m) controlling the environment under which the replication is effected to ensure repeatability; and
- n) verification that each copy is an exact replica.

7.1.3.2 Configuration identification

Configuration identification shall provide a process to uniquely identify software configuration items throughout the software life cycle. This process should include the identification of the type of release and associated configuration control requirements.

NOTE Prototype or experimental software should be uniquely identified and distinguished from production software.

7.1.3.3 Change control

The organization shall establish and maintain a change control system for software products, which provides the capability to:

- a) identify uniquely the version of each configuration item;
- b) identify the configuration of software products during development, and upon release, delivery, or installation;
- c) manage access and changes to controlled items;
- d) provide coordination for the updating of multiple products in one or more locations, as required; and
- e) identify and track to closure all actions and changes resulting from a problem report.

7.1.3.4 Configuration status accounting

The organization shall establish and maintain configuration status accounting procedures to record, manage, and report on:

- a) the status of software, the support environment, and related hardware items;
- b) the change requests and the implementation of approved changes;
- c) each formal software baseline, including:
 - the specific source and executable code items by version;
 - the support software;
 - build instructions;
 - change or problem report summary;
 - associated software documentation for the specific release;
 - test procedures and results;
 - associated development and verification tools;
 - interfaces to other software products and to target computer hardware; and
 - the development and target computer environments (hardware and software).
- d) the software releases and the differences between each release.

7.1.3.5 Configuration audit

Configuration audits are performed to determine whether a product conforms to its performance and functional requirements, and the as-built technical documentation. The configuration audit of software shall be performed, as planned, to verify:

- a) all design and development activities, data, and documents are complete and records retained;
- b) all problem reports and change requests are identified and handled;
- c) the build instructions to ensure the deliverable object code can be regenerated from the source code;
- d) software requirement deviations are recorded and approved;
- e) the software can be loaded into the target computer and initialized;
- f) the software was tested and accepted in accordance with the requirements;
- g) traceability exists from the software product to the requirements;
- h) the software and its media are correctly identified;
- i) the software and its media are corruption free;
- j) the software and its media are free of malicious code (e.g., viruses, mal-ware); and
- k) the source code is identified and under configuration control.

NOTE 1 These objectives can be verified by the accumulation of evidence throughout the software life cycle.

NOTE 2 Process audits of the configuration management system are addressed through internal audit (see 8.2.2) and/or the planned audit activities defined in Clause 7.1.

7.1.4 Control of work transfers

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

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

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

The organization should plan the approach for deriving requirements from prototypes and demonstrations, as applicable [e.g., a prototype of a Graphical User Interface (GUI) is used to establish software requirements].

7.2.2 Review of requirements related to the product

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

The organization's process for the review of requirements shall include:

- a) coordination with stakeholders;
- b) methods for agreeing on requirements and levels of traceability; and
- c) methods for authorizing changes to software related requirements.

7.2.3 Customer communication

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

7.3 Design and development

7.3.1 Design and development planning

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

Design and development planning shall include:

- a) the definition and management of the entry and exit criteria, and associated inputs and outputs, including documentations for each phase of the design and development process; and
- b) the level(s) of forward and backward traceability appropriate for the software (e.g., that each software requirement is traced from systems requirements through detailed requirements, design, code, and verification).

7.3.2 Design and development inputs

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

Inputs to design and development shall include the allocation of requirements to be implemented in the software. Software requirements, including interface requirements, shall be verifiable, traceable to, and consistent with higher level requirements. Requirements which cannot be traced back to the higher level requirements shall be identified as derived requirements and communicated, as appropriate, to the stakeholders.

The results of the requirements review shall be communicated to applicable stakeholders to ensure that the needs and expectations have been adequately captured and expressed.

NOTE The following are examples of software design and development inputs: system architectural design, system safety analysis, security and reliability analyses, critical items, external interface control documents, and trade studies.

7.3.3 Design and development outputs

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

The required outputs from the design and development activities shall be defined (see 7.3.1), documented, and reviewed, as planned. The organization shall evaluate the software critical items, including any key characteristics against planned levels or thresholds for the software product and process. The outputs shall be evaluated for correctness, completeness, and consistency with the software requirements.

NOTE The following are examples of software design and development outputs: architectural design, design robustness requirements, detailed design, source and executable code, safety analysis, security and reliability analyses, external interface control documents, user guides, installation instructions, and plans.

7.3.4 Design and development review

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

7.3.5 Design and development verification

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

When non-developmental software is integrated into deliverable products, end item requirements allocated to the non-developmental software shall be verified as part of the end item verification/validation. Non-developmental software, including any supporting documentation (e.g., version description data, user manual, verification data), shall be identified and configuration controlled to support conformity, certification, and customer acceptance.

In some cases, the product cannot be fully verified by testing (e.g., where safety critical software cannot be tested under actual circumstances without risking serious consequences or perhaps the circumstances are rare and difficult to simulate). Due to the inability to test some software products exhaustively and conclusively, the organization shall use alternative methods of verification (e.g., analysis, inspection, demonstration, higher level integration, simulation testing).

7.3.6 Design and development validation

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

In some cases, the product cannot be fully validated by testing (e.g., where safety critical software cannot be validated under actual circumstances without risking serious consequences or perhaps the circumstances are rare and difficult to create). Due to the inability to validate some software products exhaustively and conclusively, the organization shall use alternative methods of validation (e.g., analysis, inspection, demonstration, higher level integration, modeling, simulation).

The type and extent of validation methods used shall be proportionate with the risk and consequences of design and development failures. Any differences between the validation environment and the actual application environment shall be documented and evaluated.

7.3.6.1 Design and development verification and validation testing

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

The test environment shall be documented and controlled to ensure repeatability.

NOTE 1 Verification and validation testing should be appropriate to the size, criticality, and scope of the product.

NOTE 2 An approach for regression testing should be documented for retesting software aggregates that have been changed. Regression testing should be appropriate to the size, criticality, and scope of the change.

7.3.6.2 Design and development verification and validation documentation

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

7.3.7 Control of design and development changes

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

A design and development change process that accommodates effective change control for software shall be developed and implemented. The process should contain a scheme for categorizing and prioritizing the changes. Each change should be classified by the category and priority to facilitate trend analysis and problem resolution.

Design and development changes to software shall be evaluated for impact to applicable products and processes within the life cycle. The evaluation should consider potential impacts to aggregate system performance, safety, reliability, and maintainability.

If a software change results from a nonconformance, the provisions of the nonconformance handling process (see 8.3) shall be invoked.

7.4 Purchasing

7.4.1 Purchasing process

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

7.4.2 Purchasing information

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

The organization shall ensure that purchasing information is approved by the impacted functions within the organization (e.g., purchasing, software engineering, software quality, configuration management).

Purchasing information should include applicable standards (e.g., communication protocols, architectural specifications, interface requirements, engineering standards, regulatory guidance, safety and security standards) used for software product realization.

7.4.3 Verification of purchased product

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

NOTE For the verification of COTS software integrated into deliverable software, refer to Clause 7.3.5.

7.5 Production and service provision

For software, the term “production” is intended to cover only the deployment of approved, released software for loading into the target computer system or device.

7.5.1 Control of production and service provision

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

The organization shall have a documented procedure for the delivery of configuration-controlled software products. Delivery may be achieved by physical movement of media or hardware containing software or by electronic transmittal. The procedure may utilize tools to ensure the integrity of the transfer, storage, and retrieval of the software products, as applicable.

When software product is delivered in hardware, the organization shall have a documented procedure for loading the software into the hardware.

Records with evidence of the software load integrity verification shall be maintained (see 4.2.4).

7.5.1.1 Production process verification

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

The organization shall verify production procedures that load software. The production procedures shall validate the correctness and integrity of the load operation and the ability to initialize the target system after the load.

NOTE The configuration audit, sometimes referred to as a software conformity review or first article inspection, is defined in Clause 7.1.3.5.

7.5.1.2 Control of production process changes

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

Changes made to software loading and verification procedures should be verified by personnel who understand the software load requirements. Changes shall be made in accordance with formal configuration control procedures.

7.5.1.3 Control of production equipment, tools and software programs

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

Equipment (including test equipment) and tools that transfer and verify executable software from computer readable media (e.g., compact disc, server resident files) to the target system shall be validated to ensure the integrity of the load operation.

NOTE The replication of media is covered in Clause 7.1.3.1.

7.5.1.4 Post-delivery support

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

NOTE For software repair scheme, refer to Clause 7.1.3 for configuration management requirements.

7.5.2 Validation of processes for production and service provision

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

7.5.3 Identification and traceability

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

The organization shall identify the software configuration with the target system in which it is installed.

7.5.4 Customer property

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

7.5.5 Preservation of product

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

The organization shall preserve software products in accordance with configuration management planning that includes, as applicable:

- a) archival and retrieval;
- b) disaster recovery and contingency planning;
- c) degradation of the media;
- d) storage and handling of software media in a protected environment due to factors (e.g., temperature, humidity, electromagnetic and electrostatic discharge);

- e) encryption/decryption;
- f) compression/decompression;
- g) protection from software viruses and malicious acts; and
- h) the period of obligation of the organization to supply media copies and the capability of reading media copies.

7.6 Control of monitoring and measuring equipment

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

The organization shall determine and document how test equipment used for validation, verification, or acceptance of deliverable software product is developed, maintained, and controlled.

NOTE Calibration is a verification technique that is not typically applicable to software; however, it may be applicable to hardware and test or simulator software used to test and validate the deliverable software, related hardware, and systems.

8 Measurement, analysis and improvement

8.1 General

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

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

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

8.2.2 Internal audit

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

The organization's internal audit program shall include the software aspects of the quality management system.

NOTE Project-level audits may be examined and used as evidence in internal audits; however, they do not completely fulfill this internal audit requirement.

8.2.3 Monitoring and measurement of processes

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

8.2.4 Monitoring and measurement of product

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

8.3 Control of nonconforming product

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

The organization shall establish documented procedures for control and disposition of nonconforming software products, including:

- a) recording discovered nonconformance;
- b) analyzing possible impacts to other parts of the software/system;
- c) evaluation and prioritization of nonconformities;
- d) notification of responsible parties to ensure proper resolution tracking;
- e) methods for verifying product modifications;
- f) maintaining records of the reason and authorization for each modification; and
- g) recording final disposition, which can include:
 - modification to meet the requirements;
 - concurrence by the customer, if the disposition results in a departure from the contract requirements;
 - acceptance by deviation or waiver;
 - treatment as a conforming product after amendment of requirements; and
 - rejection.

Problems identified with non-developmental software should be communicated to the provider of the item, based on risk.

8.4 Analysis of data

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

8.5 Improvement

8.5.1 Continual improvement

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

8.5.2 Corrective action

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

8.5.3 Preventive action

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

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