

## SLOVENSKI STANDARD SIST EN 9116:2016

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Aeronavtika	Aeronavtika - Zahteve za sporočilo o spremembah				
Aerospace series - Notice of Change (NOC) Requirements					
Luft- und Raumfahrt - Anforderungen an eine Änderungsmitteilung					
Série aérospatiale - Avis de modification DARD PREVIEW					
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49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general			
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#### **SIST EN 9116:2016**

# EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

# EN 9116

December 2015

ICS 49.020

**English Version** 

## Aerospace series - Notice of Change (NOC) Requirements

Série aérospatiale - Avis de modification

Luft- und Raumfahrt - Anforderungen an eine Änderungsmitteilung

This European Standard was approved by CEN on 26 September 2015.

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.

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

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#### SIST EN 9116:2016

#### EN 9116:2015 (E)

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#### **European foreword**

This document (EN 9116:2015) 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 European 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 June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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

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#### RATIONALE

This European Standard was created to define the process requirements and data expectations for the submission of proposed changes in design information that requires concurrent approval of the design authority, when the design authority is different from the design activity. This European Standard provides for the organizational requirements, definitions, and data submission, including suggested data descriptions and format (paper or electronic submission).

This European Standard was created to provide for the uniform submittal of change notifications and/or approval when contractually invoked at any level or as guidance within the aviation, space, and defence industries. This European Standard can be invoked as a stand-alone requirement or used in conjunction with 9100-series standards (i.e., 9100, 9110, 9120).

To assure customer satisfaction, aviation, space, and defence industry organizations must produce and continually improve safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the industry and the resulting diversity of regional/national requirements and expectations have complicated this objective. End-product organizations face the challenge of assuring the quality and integration of product purchased from suppliers throughout the world and at all levels within the supply chain. Industry suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The aviation, space, and defence industry established the International Aerospace Quality Group (IAQG) for the purpose of achieving significant improvements in quality and safety, and reductions in cost throughout the value stream. This organization includes representation from companies in the Americas, Asia/Pacific, and Europe. This international standard has been prepared by the IAQG.

A change process consists of design change management and/or manufacturing process change to a previously approved design (baseline configuration) of the product. This document standardizes requirements for Notice of Change (NOC) data definition and documentation for the aviation, space, and defence industries. The establishment of common requirements for use at all levels of the supply-chain is intended to improve quality, safety, and decrease costs by the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.

#### 1 Scope

#### 1.1 General

The aviation, space, and defence industries rely on the development and manufacture of complex products comprised of multiple systems, subsystems, and components each designed by individual designers (design activities) at various levels within the supply chain. Each design activity controls various aspects of the configuration and specifications related to the product. When a change to design information is requested or required, the change has to be evaluated against the impacts to the higher-level system.

Proposed changes to design information that the design activity identifies to be minor and have no effect on their product requirements or specifications have the potential to be concurrently implemented and approved, where authorized to do so. Changes that affect customer mandated requirements or specifications shall be approved prior to implementation. In many cases, the design activity is not the design approver or authority; ultimate approval may be several layers above the design activity. The typical flow of design requirements to the supplier, from the design authority, and the change notification flow is presented in Figure 1.

#### **REQUIREMENTS**

# Supplier Integrator Design Holder Design Authority iTeh STANDARD PREVIEW (standards it charies) (standards it charies) SIST EN 91162016 Sist EN 91162016 Standards it charies)

Design Activity https://standards.ite Change Evaluators (Customer) f-46c5-8fa1-3bfeec9356ca/sist-en-9116-2016

**Design Authority** 

#### Figure 1 — Typical design requirements and change notification flow

Submitting NOC data either electronically or conventionally on paper is subject to the terms and conditions of the customer's contract. This also includes, where applicable, data access under the regulations of export control.

The process of exchanging, coordinating, and approving NOC data varies with the multiple relationships and agreements among all organizations concerned. The information provided by this European Standard forms the architecture for submitting and managing data that allows for concise and accurate communication using various methods. One objective of this European Standard is to provide the definition of a data set that can be integrated into any form of communication (e.g., electronic data interchange, submission of conventional paper forms).

If all or part of this European Standard is invoked in the contract, design activities and design holders (i.e., the organization responsible for the design) that have responsibility for change management of products used on other higher-level designs shall use the information and processes defined in this European Standard, and in accordance with the contract, for submitting change notifications to customers.

#### 1.2 Application

This European Standard defines the common NOC requirements for aviation, space, and defence organizations. Included are the requirements that an internal/external supplier or subcontractor shall

use when submitting a NOC to the customer for either change authorization or notification. A NOC informs the customer of physical or functional (including software) changes to an established baseline configuration. Retention of the NOC establishes a means of configuration control and captures the evolution of the part. This requirement is of utmost importance in commercial/civil aviation products where changes to type certificated products are mandated by regulations. However, these same concepts are also required to some degree in defence and space applications per contractual requirements.

This European Standard is not applicable to products that are manufactured by a supplier to their customer's designs and processing requirements (also known as build-to-print). Change requests to this type of product shall be formally submitted to the customer and approved via the customer's change request process. Additionally, this European Standard is not applicable to commercial parts (off-the-shelf items not specifically designed for aviation, space, or defence products) for which changes in product definition is not affected or known, but change to commercial parts that are known (i.e., change in definition from one commercial part number to a different commercial part number) shall be processed in accordance with this European Standard.

When this European Standard is applied to an organization that distributes product, then this European Standard shall be a requirement from the distribution organization to the organization from which the product is procured. The distribution organization may act as a conduit for the NOC or the design activity (supplier) may work directly with the design authority (customer). The distributor should be compliant with the 9120 standard, as defined by customer requirements.

Application or implementation of this European Standard in any form, either expressed or implied, is not allowed for product which has escaped the supplier's quality system.

#### 2 Normative references

#### <u>SIST EN 9116:2016</u>

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. When a conflict in requirements between this document and referenced standards exists, the requirements of this document shall take precedence. Nothing in this document, however, supersedes applicable laws and regulations, unless a specific exemption has been obtained.

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

EN 9110, Quality Management Systems — Requirements for Aviation Maintenance Organizations

EN 9120, Quality Management Systems — Requirements for Aviation, Space, and Defence Distributors

NOTE Equivalent versions (e.g., AS, EN, JISQ, SJAC, NBR) of the IAQG standards listed above are published internationally in each sector.

ANSI/ASME Y14.24, *Types and Applications of Engineering Drawings* [document available from American National Standards Institute (ANSI); <u>www.ansi.org</u>]

ARP9034, A Process Standard for the Storage, Retrieval and Use of Three-Dimensional Type Design Data

EIA – 649, *National Consensus Standard for Configuration Management* [document available from Electronic Industries Alliance (EIA) Publications; <u>www.eia.org</u>]

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary

RTCA/DO-254 (EUROCAE ED-80), *Design Assurance Guide for Airborne Electronic Hardware* [document available from Radio Technical Commission for Aeronautics Inc.; <u>www.rtca.org</u>]

#### **3** Terms and definitions

Definitions for general terms can be found in ISO 9000 and the IAOG Dictionary, which is located on the IAOG website. An acronym log for this European Standard is presented in Annex A. For the purpose of this European Standard, the following shall apply:

#### 3.1

#### baseline configuration

the design definition for the physical product and its performance requirements from which design change control can then take place. This is determined jointly by the customer and the design activity

#### 3.2

#### change evaluator

the person authorized on behalf of the design authority to assess the potential impact of the change(s), evaluates changes for the potential impact on the fit, form, or functionality of the part, system, or assembly and failure to meet the customer requirements. The change evaluator could also be the customer or the producer of the end item and/or the design authority.

#### 3.3

#### critical items

deliverable

those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

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#### 3.4

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any design data provided to the customer which represents the product provided

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#### design activities

**design activities** 3bfeec9356ca/sist-en-9116-2016 the supplier design activity or subcontractor that owns the design and provides a deliverable to the customer

#### 3.6

#### design authority

an organization with formal authority for the design, validation, and service support of a product

Note 1 to entry: In civil aviation, this is the organization responsible for the design of articles or for changes thereto that is the holder of a design approval granted by a regulatory authority [i.e., Type Certificate (TC); Supplemental Type Certificate (STC); Parts Manufacturer Approval (PMA); Technical Standard Order (TSO)/European Technical Standard Order (ETSO); European Part Approval (EPA); European Aviation Safety Agency (EASA) Part 21 - "Design Organization Approval Holder", or equivalent].

#### 3.7

#### end item

the item that is ultimately delivered to the end user (e.g., vehicle, propulsion system)

#### 3.8

#### key characteristics

an attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility that requires specific actions for the purpose of controlling variation (refer to section 3.3)

#### 3.9

#### mandatory

a requirement that shall be fulfilled or common transferable data that shall be provided and systematically recorded

#### 3.10

#### optional

any data field that is not defined as mandatory by this European Standard, including any special data fields requested by the customer or the originator

#### 3.11

#### product

any aviation, space, and defence vehicle, engine, propeller, airframe part or equipment (within that vehicle) to be used in operating or controlling a vehicle in flight. The result of a process, which in the context of this European Standard, includes finished detailed parts, assemblies, forgings, and castings.

Note 1 to entry: Product may include software that is embedded or field loadable in the end item.

#### 3.12

#### Source Control Drawing (SOCD)

provides an engineering description, qualification requirements, and acceptance criteria for items procurable from a specialized segment of industry, that provide the performance, installation, interchangeability, or other characteristics required for critical applications. Furthermore, it may provide a list of approved sources of supply and the vendor's item identification that have been qualified and approved for use in the critical application(s).

Note 1 to entry: Adapted from ANSI/ASME Y14.24.

#### 3.13

#### special process

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a process where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or has been delivered

#### 4 Configuration change definitions

#### 4.1 Changes to baseline configuration

A baseline configuration is an agreed configuration definition against which compliance was shown (e.g., certification baseline). Baseline configuration is captured by design data and is typically retained by the design activity. The baseline configuration shall clearly define the design characteristics and performance requirements of the product, including acceptance conditions of the products to the lowest level of detail necessary to produce the product and ensure compliance with all applicable requirements of the customer.

All changes to previously customer accepted baseline configurations shall be evaluated and approved. Until the requirements of section 5 are satisfied, each change (from the lowest level in the supply chain) shall be submitted to the customer and ultimately to the design authority for concurrence to implement. Figure 2 depicts the process when customer delegated change evaluation is not obtained and Figure 3 is for organization's with customer delegated change evaluation approval.

The product baseline configuration from which changes will be evaluated may include:

a. SOCD.

b. Product specifications and drawings, including electronic data sets and supersession.

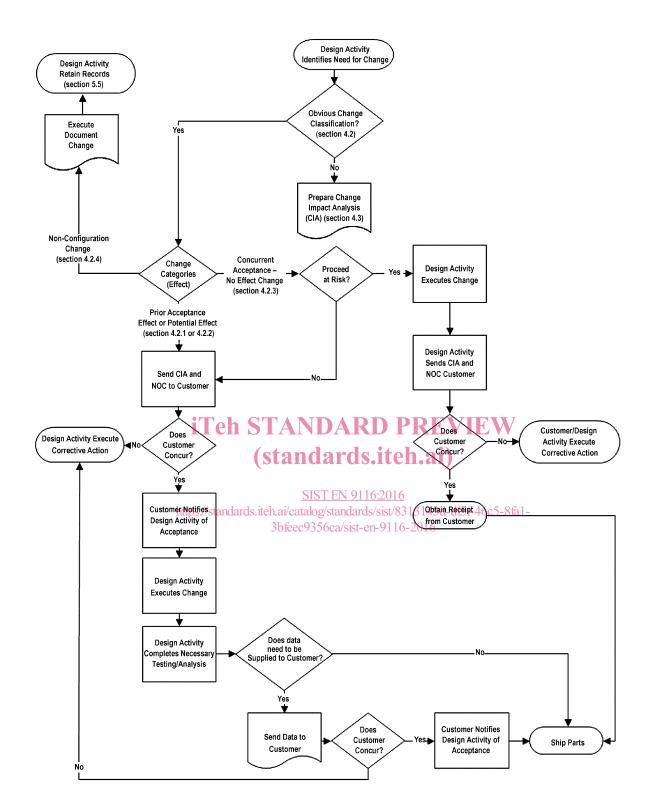
- c. Bill of Materials (BOM), including definition of spare or substitute parts which may be used in repair, but have different definition than those of baseline configuration parts.
- d. Process specifications in accordance with contractual requirements.
- e. Manufacturing methods, as shown on engineering drawings.
- f. Product usage/function/systems application, which may include:
  - Effect of product failure on system application.
  - Identification of key components, processes, and/or characteristics, as applicable.

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**Figure 2 — Flow chart for Notice of Change (NOC) submittal** (Design Activity is NOT Authorized to Analyze Changes on Behalf of Customer)

NOTE Design activity <u>does NOT meet</u> criteria of section 5.