SLOVENSKI STANDARD
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Upravljanje programov - Definicija upravičenosti in razvrščanja - Vodilo za pripravo načrta za definicijo upravičenosti in dokumentacije definicije upravičenosti

Programme Management - Definition Justification and Qualification - A guide to drawing up the definition justification plan and of the definition justification dossier

Programm-Management - Festlegung, Nachweis und Qualifikation - Richtlinien zur Erstellung des Konstruktionsstands-Nachweisplans und der Konstruktionsstands-Nachweisunterlage

Management de Programme - Justification et Qualification de la Définition - Guide pour l'élaboration du plan de justification de la définition et du Dossier de justification de la Définition

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Programme Management - Definition Justification and Qualification - A guide to drawing up the definition justification plan and of the definition justification dossier

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

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European foreword

This document (prEN 9215:2020) 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 document is currently submitted to the CEN Enquiry.

1 Scope

This document sets forth the general rules applying to the justification of the definition of a product (tangible or intangible) and specifies the content of the Definition Justification Plan (DJP) and the Definition Justification Dossier (DJD).

It is applicable to all products designed and developed to fulfil the requirements of a customer expressed in a (Need) Technical Specification. Industrials are advised to apply the following principles to their own needs for justification in their internal customer/supplier relations.

Clause 5 presents the concepts and the documents associated with the justification of the definition and qualification processes.

Clause 6 summarizes the role and the contractual nature of the qualification of the definition.

Clause 7 gives details of the qualification of the definition process, while Clause 8 positions this process in the programme development logic.

The document also describes the differences between the justification and the qualification of the definition and other notions, such as verification, validation or acceptance (Clause 9).

Clause 10 is a guide to the establishment and maintenance of the documents associated with the justification of the definition and qualification processes. Information related to the certification process, even if it is out of the scope of the present document, is also presented in Clause 10, because this process has certain similarities with the justification of the definition and qualification process.

This document belongs to the documents supporting the EN 9200 relating to Project Management Specification.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/ui

— IEC Electropedia: available at http://www.electropedia.org/

3.1
document acceptance
decision by which the customer agrees that the document complies with the contractual requirements

Note 1 to entry: In the case of document acceptance, customer's responsibility is not committed. The document author remains responsible for its content and is in particular in charge of fixing any non-conformity detected after acceptance decision.

Note 2 to entry: Without any response from the customer within a time limit previously specified, the document is considered as de facto accepted.

3.2
product acceptance
contractual decision by which the customer agrees that the product is manufactured according to its qualified definition and the agreed deviations and waivers, and it is free of defects when delivered by the suppliers

3.3
certificate
document formalizing the definition approval issued by the Authority when the designer demonstrates that the product complies with the applicable regulations

3.4
certification
acknowledgement, formalized by a certificate written internally or by an accredited third party, that the subject of the certification conforms to specified requirements and is acceptable for operational use

Note 1 to entry: The certification may apply to a product, a service, a system, a management system or a person.

Note 2 to entry: This acknowledgement does not systematically authorize actual use. E.g.: regarding air transports, a specific second certificate issued by national authorities is necessary for the conformance to its operational requirements.

3.5
definition justification dossier (DJD)

document or file gathering all the information of design and tests demonstrating that the definition of the product described in its Definition Data File fulfils all the requirements of the (Need) Technical Specification [(N)TS]

3.6
justification of the definition
process by which the supplier collects arguments and evidence, coming from product verification and validation activities, in order to demonstrate that the product definition fulfils all the requirements of the customer's (Need) Technical Specification [(N)TS]

Note 1 to entry: Evidence acquisition activities are planned in a Definition Justification Plan (DJP) submitted to customer approval. However, DJP elements deemed design-critical regarding costs and time shall be included in the contract and are de facto approved by the customer.

Note 2 to entry: Collected evidence and conclusions are gathered in a Definition justification dossier (DJD) submitted to customer acceptance.

Note 3 to entry: The justification of the definition does not add specific technical activities for the supplier. It is based on the results of the product verification and validation technical activities carried out in any case by the supplier.

3.7
definition Justification Plan (DJP)
document presenting how and when (types of means of compliance, types of activities, etc.) will be justified that the definition of the product fulfils all the requirements of the (Need) Technical Specification [(N)TS]

3.8
qualification pronouncement
act whereby the customer certifies, on the basis of the theoretical and experimental justifications presented by the supplier in the DJD and the Manufacturing and Control Justification File, and on the customer's qualification tests, that the definition of the product (contained in the Definition File) fulfils all the requirements expressed in the (Need) Technical Specification and that this definition is producible

Note 1 to entry: The pronouncement can be a formal document issued by the client or simply an explicit mention in a qualification review report.

Note 2 to entry: The qualification pronouncement ends the development contract.

Note 3 to entry: This pronouncement is worth customer's commitment to the supplier regarding the qualified definition. This definition becomes the reference definition on the basis of which the serial production specimens are made.

Note 4 to entry: If the definition changes, because of the customer, after the qualification pronouncement and after the production launching, the customer should bear the cost of the resumption of production related to the changes.

3.9
qualification of the definition
process whose objective is to demonstrate that the product definition fulfils the requirements of the (Need) Technical Specification and is producible. This process encompasses the activities of the justification of the definition (theoretical and experimental) carried out by the supplier and activities carried out by the customer. Customer activities consist on the one hand by the analysis of justification of the definition elements and producibility justification elements transmitted by the supplier, and on the other hand by so-called qualification tests in a customer environment

Note 1 to entry: The qualification tests are conducted by the customer, on samples of the product called qualification samples, in an environment representative of the operating environment. The scenarios used during these tests may go beyond those defined in the supplier's Definition Justification Plan (additional testing facilities, extended domain, etc.). During these tests, the supplier may be present in support, for the implementation of the product as part of a support service.

3.10
product validation
process which demonstrates through objective evidence (results of inspections, measurements, analyses, tests, etc.) that the product as designed fulfils operational need in the intended operational environment

Note 1 to entry: Validation activities may be carried out in real or simulated operational environment.

Note 2 to entry: Product validation answers the question "Has the right product been built?"

3.11
product verification
process which demonstrates through objective evidence (results of inspections, measurements, analyses, tests, etc.) that the product as designed is compliant with specified requirements

Note 1 to entry: Product verification differs from requirements verification.

Note 2 to entry: Product verification answers the question "Is the product built right?".

4 List of acronyms

AC Acceptance Conditions
AS Acceptance Specification
CDR Critical Design Review
CF Certification File
COTS Component Off-The-Shelf
CP Certification Plan
CR Certification Review
DDF Definition Data File
DDFi intermediate Definition Data File
DGA *Direction Générale de l'Armement* [French Directorate General for Armaments]
DJCF Design Justification Choice File
DJD Definition Justification Dossier
DJP Definition Justification Plan
FPS Functional Performance Specification
MIJF Manufacturing and Inspection Justification File
(N)TS (Need) Technical Specification
ORR Operational Readiness Review
PBS Product Breakdown Structure
PDR Preliminary Design Review
PTS Product Technical Specification
QR Qualification Review
SoW Statement of Work
TOEV Technical and Operational Evaluations
TRR Test Readiness Review
V&V Verification and Validation
WS Work Specification [*Cahier des Prestations*]

5 Presentation of the associated concepts and documents

5.1 Qualification of the document

5.1.1 Purpose of the qualification of the definition

For the customer, the qualification of the definition:

— ensures that the definition of the product covered by the development contract fulfils the technical requirements of the contract; and

— uses the output from the certification process to consider the fulfilment of the regulatory requirements of the product (see 10.4) when the product is subject to certification.

For the supplier, it limits the demonstration costs and enables the customer's agreement to be obtained on the product definition on a clear and negotiated basis from the very start of the contract.

The pronouncement of the qualification of the definition formally recognizes the success of the development and constitutes the milestone representing the end of the development contract.

It constitutes an "OK to series production" on the basis of the qualified definition.

5.1.2 Difference from other types of qualification

The term "qualification" could not be used without specifying the purpose to be qualified, because qualification covers a number of diverse notions that it is important to distinguish from one another.

Unlike the qualification of the definition, operational qualification (see Figure 4) corresponds to the use of the product in the operational environment. Operational qualification covers the Technical and Operational Evaluations (TOEV) made by the end user (the supplier may provide support). The purpose of operational qualification is to demonstrate that the product:

— is operable in an operational context and environment;

— possesses the expected operational capabilities (a capability is described by a set of operational scenarios and processes representative of the use cases of the product); and

— achieves a level of performance required by the users (according to criteria, measurements, service levels, etc., defined by the users).

Operational qualification is established on the basis of the operational concept document, and in particular the description of the operational scenarios.

The pronouncement of the qualification of the definition is a prerequisite of operational qualification. The product subject to operational qualification is a representative sample of the series definition or the first article. Operational qualification can be pronounced by the buyer and the users (decision to adopt) after the operational readiness review (ORR).

The purpose of the **qualification of the production system** is to demonstrate that the production system is capable of producing samples of the product in keeping with its definition and the objectives of the programme at controlled risk levels. The qualification of the production system takes place in parallel and is consistent with the qualification of the definition. The qualification of the production system takes account of the requirements of industrialization and of the manufacturing rules.

The approach to the qualification of the production system guarantees that the factors of the industrial process (procedures, means of manufacturing and integration, means of inspection, the environment) are operated under controlled conditions and can guarantee the compliance and the reproducibility of the products. The qualification of the production system is established on the basis of the manufacturing and inspection justification file (MIJF). The supplier can pronounce the qualification of the production system at the end of a review.

The **qualification of a manufacturing process** attests that the process fulfils the specified requirements (characteristics, level of performance, reliability, etc.) on the basis of the evidence produced. It is a part of the qualification of the production system.

Reduced qualification is a material qualification relative to a subset of requirements for resistance to the environment, on a complete product or on a representative part of the product. When such a qualification takes place, it is one of the steps of the qualification of the definition. Under conditions of minimal safety, it enables intermediate milestones (e.g. first flight readiness, etc.) to be passed.

Material qualification is the complete qualification of one or more items of equipment in relation to the requirements for resistance to the environment. It is part of the qualification of the definition (see the RTCA DO-160, for example).

5.2 Justification of the definition

5.2.1 Concept

Justification of the definition is a part of the efforts made to control development costs.

The justification of the definition of a product consists of providing evidence and proof demonstrating that the product definition fulfils the requirements to be met.

To this end, the supplier proposes an approach that justifies the product definition. This approach consists in:

— reaching a common agreement on the requirements, or even the objectives, contained in the (need) technical specification ((N)TS) and in the regulation, for which justification of the product definition is necessary, and ensuring that they are properly and identically understood;

— identifying the risks of failing to fulfil the requirements or failing to achieve the objectives, and estimating their gravity and probability of occurrence; and

— by common agreement, producing a common framework of reference for the elaboration of the documents to provide, i.e.:

  — the Definition Justification Plan (DJP), which precises how and when each response to the expressed requirements will be justified (nature of the work to be done and the corresponding resources), in view of the identified and accepted risks;

  — the Definition Justification Dossier (DJD), which provides access to the agreed justification information and contains a review of the justifications acquired.

For products subject to certification, the supplier makes sure that the proposed approach includes all the factors associated with the certification process in order to optimize the justifications (studies, tests, documentation, etc.) and to make sure they are consistent with the needs expressed by the customer and the Authorities (see 10.4).

The arguments and evidence, based on the results of the verification and validation works of the product (see Clause 9), collected by the supplier during the development of the product and compiled in the DJD, contribute to the pronouncement of the qualification of the definition of this product by the customer.

The justification of the definition is based on theoretical factors, experimental factors, experience acquired in similar developments and the supplier's know-how. If necessary, it takes the justifications already obtained for the constituent parts of the product concerned into consideration.

5.2.2 Differences with other related notions

5.2.2.1 Justification of the definition versus requirements justification

The justification of the definition shall not be confused with, and bears no direct relation to, the requirements justification.

The purpose of the requirements justification of a requirements specification document (Functional Performance Specification (FPS), (N)TS, Product Technical Specification (PTS), etc.) is to:

— trace and validate the requirements in relation to the requirements of a higher level, by making sure that they are implemented correctly and completely; and