SLOVENSKI STANDARD
SIST EN 9145:2019

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Aeronavtika - Zahteve za napredno načrtovanje kakovosti izdelkov in proces odobravanja proizvodnih delov

Aerospace series - Requirements for Advanced Product Quality Planning and Production Part Approval Process

Luft- und Raumfahrt - Anforderungen an die Produktqualitätsvorausplanung und das Produktionsteil-Freigabeverfahren

Série aérospatiale - Exigences pour une planification avancée de la qualité produit et un processus d'approbation des pièces de production

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ICS:

03.120.01	Kakovost na splošno	Quality in general
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Aerospace series - Requirements for Advanced Product Quality Planning and Production Part Approval Process

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This European Standard was approved by CEN on 28 August 2017.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN 9145:2018) 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of an identical text or by endorsement, at the latest by *April 2019*, and conflicting national standards shall be withdrawn at the latest by *April 2019*.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Rationale

This standard was created to define the aviation, space and defence process requirements for Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP). The APQP aspects of this standard define a methodology for ensuring that the product development processes deployed throughout the aviation, space and defence industries are fully integrated phased processes that extend from concept and design through manufacturing process planning and execution and on into product use, service and customer feedback. The PPAP is an output of APQP confirming that the production process has demonstrated the potential to produce products that consistently fulfil all requirements at the customer demand rate.

Foreword

To assure customer satisfaction, the aviation, space and defence industry organizations must produce and continually improve safe, reliable products that equal 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 of and integration of product purchased from suppliers throughout the world and at all levels within the supply chain. Industry suppliers 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, delivery, safety and reductions in cost, throughout the value stream. This organization includes representation from companies in the Americas, Asia / Pacific and Europe.

This document standardizes the requirements for the Product Development Process (PDP) through the use of APQP and PPAP methodologies. The establishment of common requirements, for use at all levels of the supply chain, should result in the elimination or reduction of organization unique requirements and the resulting variation inherent in the multiple expectations.

This document has been developed by IAQG to cover a wide domain of global applicability (Aerospace & Defence); please be informed that some standards have been developed by CEN to cover specifically space systems (e.g. CEN/CENELEC TC5 EN 166XX series). For European space applications these standards may be taken into account.

0 Introduction

0.1 General

This standard specifies requirements in a structured framework to plan and complete actions of the product realization cycle which are necessary to ensure quality product(s) are delivered on time, while satisfying cost performance targets. APQP drives a quality focused approach to product development through the use of a phased planning process within which specific deliverables are established, monitored and tracked to closure, while highlighting and mitigating risks as they are identified. PPAP is an output of APQP confirming that the production process has demonstrated the potential to produce products that consistently fulfil all requirements while operating at the customer demand rate.

Successful implementation of APQP requires: management commitment and support from the beginning of the product development cycle and multidisciplinary project teams integrating all stakeholders and delivering a committed timeline for executing planned activities.

APQP has five phases (conceptually illustrated in Figure 1) starting with conceptual product needs and extending throughout the product life cycle. The actual duration of each phase will differ depending upon the scope and timing of the specific product and/or production development project. These phases are described as follows:

- Phase 1 – Planning:

  The goal of this phase is to capture customer inputs, benchmark data, lessons learned, regulatory requirements, technical specifications, company know-how and strategy into a product concept and realization plan. This includes identification of the high-level technical, quality and cost targets.

- Phase 2 – Product Design and Development:

  The goal of this phase is to translate the technical, quality and cost requirements into a controlled, verified and validated product design. Design validation is achieved using prototype, development, or production parts in test environments that can represent the customer's installation and subject the product to extreme conditions required by contract or regulation.

- Phase 3 – Process Design and Development:

  The goal of this phase is to design and develop the production processes needed to produce product that consistently fulfil technical, quality and cost requirements while operating at the customer demand rate.

- Phase 4 – Product and Process Validation:

  The goal of this phase is to validate that product fulfils the design requirements and the production processes have demonstrated the capability to consistently produce conforming product at the customer demand rate. Product validation is achieved using product produced from the defined production processes.

- Phase 5 – On-going Production, Use and Post-delivery Service:

  The goal of this phase is to ensure customer requirements are continually fulfilled through the use of process control, lessons learned and continuous improvement.

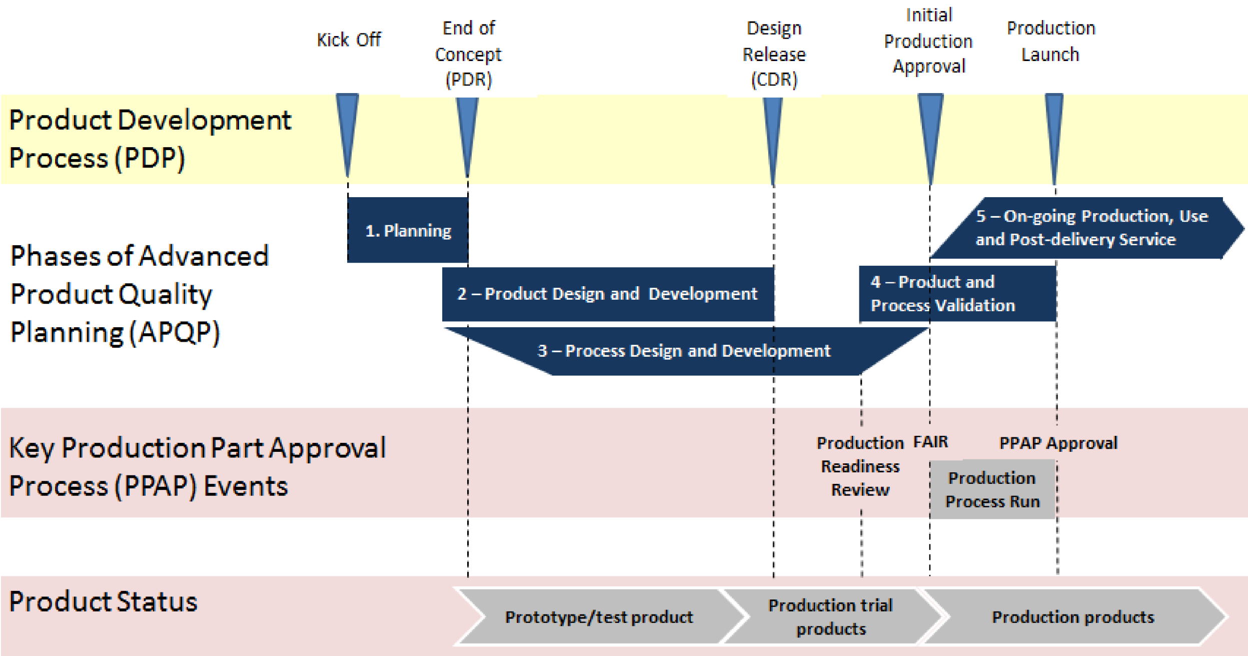
Kick Off
End of Concept (PDR)
Design Release (CDR)
Initial Production Approval
Production Launch
Product Development Process (PDP)
Phases of Advanced Product Quality Planning (APQP)
1. Planning
2 – Product Design and Development
3 – Process Design and Development
4 – Product and Process Validation
5 – On-going Production, Use and Post-delivery Service
Key Production Part Approval Process (PPAP) Events
Production Readiness Review
FAIR
PPAP Approval
Production Process Run
Product Status
Prototype/test product
Production trial products
Production products

Figure 1 — Product development process and advanced product quality planning (conceptual illustration)

0.2 Application

This standard applies to new product development efforts, but can also be applied to products currently in production where changes are planned. It can be applied to the final product or selected levels of parts (i.e. parts within an assembly as defined by the organization or customer). When this standard is flowed down as a general contractual requirement (i.e. not for a specific program or project), the scope of applicability is established between the organization and the customer.

This standard is generally not applied to standard parts or Commercial-off-the-Shelf (COTS) items. Producers and their suppliers are responsible for flow down of the requirements of this standard, as appropriate, to suppliers who design and/or produce product.

When this standard is invoked, APQP and PPAP shall continue to apply when previously approved products and processes undergo change (e.g. introduction of a new production process, change to existing production process, change of production source, addition to the existing production sources).

1 Scope

This standard establishes requirements for performing and documenting APQP and PPAP. APQP begins with conceptual product needs and extends through product definition, production planning, product and process validation (i.e. PPAP), product use, and post-delivery service. This standard integrates and collaborates with the requirements of the EN 9100, EN 9102, EN 9103 and EN 9110 standards.

The requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.

1.1 Purpose

The purpose of this standard is to establish a uniform approach to product realization across the aviation, space and defence industry ensuring that quality products are delivered on time, while satisfying cost performance targets.

1.2 Convention

The following conventions are used in this standard:

— the word “shall” indicates a requirement;

— the word “should” indicates a recommended action (content or path), but not mandatory application;

— words “typical”, “example”, “for reference” or “e.g.” indicate suggestions given for guidance only;

— “NOTES” are used for additional clarification;

— words or phrases with specific meaning pertaining to this document are defined in 3 (Terms and definitions).

2 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.

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

EN 9102, *Aerospace series — Quality systems — First article inspection requirements*

EN 9103, *Aerospace series — Quality management systems — Variation management of key characteristics*

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

EN ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

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

IAQG Supply Chain Management Handbook (SCMH) – http://www.sae.org/iaqg/:

— Advanced Product Quality Planning (APQP);

— Aerospace Advanced Product Quality Planning (APQP) Manual.

Advanced Product Quality Planning and Control Plan; APQP Second Edition; Automotive Industry Action Group (AIAG); www.aiag.org.

ASTM E 2782, *Guide for Measurement Systems Analysis (MSA)*

IEEE 1490:2011, *Guide — Adoption of the Project Management Institute (PMI) Standard; "A Guide to the Project Management Body of Knowledge (PMBOK Guide)" — Fourth Edition; www.ieee.org*

SAE J1739, *Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)*

3 Terms and definitions

Definitions for general terms can be found in EN ISO 9000 and the IAQG International Dictionary (located on the IAQG website). An acronym log for this document is presented in Annex A. For the purpose of this standard, the following definitions apply:

3.1
Bill of Material
BOM
list of components and materials contained in the design record(s) of a product

3.2
Commercial Off-The-Shelf
COTS
commercially available products, defined by industry recognized specifications and standards, sold through public catalogue listings

3.3
control plan
documented description linking manufacturing process steps to key inspection and control activities. The intent of a control plan is to control the design characteristics and the process variables to ensure product quality

3.4
Critical Item
CI
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 include: safety CIs, fracture CIs, mission CIs, Key Characteristics (KCs) and maintenance tasks critical for safety (reference EN 9103 standard)

3.5
customer
organization, legal entity, or person that receives a product or service (e.g. consumer, client, end-user, retailer, beneficiary, purchaser)

3.6
deliverables
items (outputs) completed as part of the APQP process

3.7
demand rate
quantity of products required to be produced by the production organization over a specified period of time to fulfil the delivery schedule

3.8
design characteristic
those dimensional, visual, functional, mechanical and material features or properties, which describe and constitute the design of the article, as specified by drawing or Digital Product Definition (DPD) requirements. These characteristics can be measured, inspected, tested, or verified to determine conformance to the design requirements. Dimensional features include in-process locating features (e.g. target-machined or forged / cast dimensions on forgings and castings, weld / braze joint preparation necessary for acceptance of finished joint). Material features or properties may include processing variables and sequences, which are specified by the drawing or DPD (e.g. heat treat temperature, fluorescent penetrant class, ultrasonic scans, sequence of welding and heat treat). These provide assurance of intended characteristics that could not be otherwise defined (reference EN 9102 standard)

3.9
design records
records of the engineering definition / specification, which fully define the product (system, part, component, or assembly), including physical or electronic / digital drawings, electronic / digital models, software, or other associated information. This includes records of authorized engineering changes not yet incorporated into the released engineering definition / specification

3.10
design risk analysis
analytical techniques used by the design responsible organization to identify, to the extent possible, potential failure modes related to product performance (i.e. fit, form and function), durability, manufacturability and cost

3.11
Failure Mode and Effects Analysis
FMEA
structured method for analysing risk by ranking and documenting potential failure mode in a system, design, or process

The analysis includes:

— identification of potential failures and their effects;

— ranking of factors (e.g. severity, frequency of occurrence, detectability of the potential failures); and

— identification and results of actions taken to reduce or eliminate risk.

The FMEA assists in the identification of CIs as well as key design and process characteristics, helps prioritize action plans for mitigating risk and serves as a repository for lessons learned. Examples include: system FMEA, interface FMEA, design FMEA and process FMEA.

3.12
Inspection / test plan
detailed description of inspection and test activities (e.g. tolerances, methods, gages) for features or attributes to be performed during specific manufacturing operations

3.13
Key Characteristic
KC
attribute or feature whose variation has a significant influence on product fit, performance, service life or producibility; that requires specific action for the purpose of controlling variation (reference EN 9103 standard)

This definition is further explained as follows:

— KCs for a part, subassembly, or system are those selected geometrical, material properties, functional and/or cosmetic features; which are measurable and whose variation control is necessary for fulfilling customer requirements and enhancing customer satisfaction;

— process KCs are those selected measurable characteristics of a process whose control is essential to manage variation of part or system KCs.

Substitute KCs may be identified when a customer-defined KC is not readily measurable, within the production / maintenance setting and other characteristics may need to be controlled to ensure conformance.

3.14
Measurement Systems Analysis
MSA

study of the effects of selected elements of a measurement process (i.e. people, machines, tools, methods, materials, environment) on accuracy, precision and uncertainty of measurement

3.15
phase
period of time (during the PDP) in which specific processes, tasks, deliverables and outcomes of APQP occur; phases may overlap as illustrated in Figure 1; The end of a phase is indicated by fulfilment of phase deliverables (see Annex B)

3.16
post-delivery service
service rendered to the customer or to end users in support of the product's successful continuing use. This includes, but is not limited to, providing documents (e.g. maintenance manuals, service bulletins), product use training, repair or overhaul activity, service hot lines and spare parts provisioning

3.17
pre-design
set of design related activities that establishes a preliminary concept design based upon the product specifications and requirements; This may include sketches, drawings and physical or mathematical models that provide an understanding of the principle of operation and a high-level product structure

3.18
Preliminary Bill of Material (BOM)
initial BOM completed, prior to design validation and release of design record, for production use