SLOVENSKI STANDARD
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Aeronavtika - Industrializacija - Smernice za vzpostavitev proizvodne in inšpekcijske dokumentacije ter s tem povezane utemeljitve

Aerospace series - Industrialization - Guidelines for establishing the manufacturing and inspection file and the associated justifications

Luft- und Raumfahrt - Industrialisierung - Leitfaden für die Erstellung der Herstellungs- und Kontrollakte und der dazugehörigen Begründungen

Série aérospatiale - Industrialisation - Guide pour l'élaboration du dossier de fabrication et de contrôle et des justifications associées

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49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

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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 9212:2024) has been prepared by ASD-STAN.

After enquiries and votes carried out in accordance with the rules of this Association, this document has received the approval of the National Associations and the Official Services of the member countries of ASD-STAN, prior to its presentation to CEN.

This document is currently submitted to the CEN Enquiry.

Introduction

This document belongs to the documents supporting EN 9200 relating to the programme management specification.

EN 9212 is written in accordance with the documentary system linked to EN 9200 and takes account of the current and almost systematic interconnection between the manufacturing and inspection activities of the product, in keeping with quality management practices.

The manufacturing and inspection file (MIF), and the associated justifications (MIJF), form part of the output data of the industrialization process. They are intended mainly for actors of the production process and provide the justifications required by the design and development processes, and by the acquiring customer. They are elaborated by the actors of industrialization, in partnership with the actors of development and production.

1 Scope

The aim of a MIF and the associated justifications is to ensure that manufacturing and/or inspection operations are realized in a compliant and reproducible manner, in accordance with the regulations in force.

The purpose of this document is to provide a guide to the elaboration of the MIF and the associated justifications by:

— positioning them within the framework:

  o of a programme and its objectives, on the one hand,

  o of the realization of a product, on the other;

— describing, until production of the product ceases:

  o the principles and conditions applying to the elaboration and then the validation of the MIF within the framework of the industrialization process,

  o the principles and conditions applying to the elaboration and then the validation of the MIJF associated with the MIF, within the framework of the industrialization process,

  o the principles and change and control conditions applying to the MIF and the MIJF.

This document can be used for all processes or sets of processes implemented on a tangible product, which may incorporate software associated with the product. It does not apply to purely software product, commercial-off-the-shelf product (catalogue part) or service (intangible product).

This document applies more particularly to serial production. Nevertheless, the principles and conditions set forth in this document may be applied, making any necessary adaptations, to unit production or to the realization of products to meet development needs (prototypes, demonstrators, etc.).

This document covers the MIF and the MIJF of a product, including the activities related to procurement and the associated industrial means in particular.

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
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

Note 1 to entry: Applicable MSA studies can be established by several methods [e.g. bias assessment, measuring tools gage repeatability and reproducibility (Gage R&R), measurement uncertainty analysis, etc.].

Note 2 to entry: It should be demonstrated that all measurement and inspection methods included in the inspection plan are suitable and able to respond to the pace of the customer's request.

3.2
designer
physical or legal person responsible for the design of a product or service, as well as for the development of the definition data file

3.3
inspection
activities such as measuring, examining, testing or calibrating one or more characteristics of a product and comparing the results to the specified requirements (acceptance criteria) to determine whether compliance is obtained for each of these characteristics

Note 1 to entry: the four typologies of inspection are:

— inspection: examination of a system or item against a specific criterion;

— analysis: assessment based on decomposition into simple elements;

— demonstration: method of proof of performance by observation;

— test: procedure to prove performance using stated objectives criteria with pass or fail result.

3.4
definition data file
DDF
structured set of documents formalising the definition of a product

Note 1 to entry: The definition data file makes it possible to characterize the product and ensure the management of its evolutions, to bring all the necessary data (requirements, characteristics, processes, etc.) in order to prepare its manufacturing and inspection file (MIF) and its user and support documentation.

3.5
manufacturing and inspection file
MIF
set of elements and documented information materialising, in a structured way, the resources necessary for the reproducible manufacturing and inspection process of a product in accordance with its definition data file (DDF), as well as with industrial requirements and objectives

3.6
manufacturing and inspection justification file
MIJF
document or file gathering evidence demonstrating that the MIF data meets the requirements of the definition data file (DDF), the industrial performance objectives required internally or by the customer and the producibility and reproducibility requirements

Note 1 to entry: The MIJF contributes to the qualification of the production system.

3.7
manufacturer
physical or legal person responsible for the industrialization, manufacturing of a product or for the supply of a service

Note 1 to entry: The manufacturer may own the design and the definition. The manufacturer who owns the definition is a “designer manufacturer”.

Note 2 to entry: The manufacturer can also be called supplier, external provider or industrial.

3.8
manufacturing
action to elaborate, realize, assemble, integrate and inspect a product from raw materials and/or components, with resources and following processes described in the manufacturing and inspection file (MIF)

3.9
industrialization
process, in relation to the design and production processes, which allows to:

— participate in the definition of the product in order to take into account the constraints of the production system and the programme;

— design, realize and perfect the means and methods of production according to the product definition;

— depending on the requirements and the industrial performance objectives, validate, qualify or certify these means and methods;

— monitor, maintain and optimize the means and methods of production according to objectives

3.10
product logbook
documented information allowing the recording of the various data specific to each specimen of the operational product during its use

Note 1 to entry: It allows to record successive technical events.

3.11
methods
person, service or department responsible for defining, commissioning, maintaining all the means (resources, tooling, documentation) necessary and sufficient for the realization and delivery of a product

3.12
work order
WO
documented information authorizing the launch of successive manufacturing and inspection operations to be carried out to produce a part, a series of parts or a given batch of parts

Note 1 to entry: The performance of these operations is recorded in an associated log sheet.

3.13
process
sequence of correlated or interacting activities that transforms input elements into output elements according to one or more defined objectives

3.14
production
process that covers the manufacturing and inspection of a product to be delivered to the customer/acquirer, in accordance with the provisions of the manufacturing and inspection file (MIF)

Note 1 to entry: Industrialization supports production.

3.15
product
result of activities or processes

Note 1 to entry: Product categories can be services, hardware, software, processed materials, intermediate work products from elementary activities, such as documents, models, etc.

Note 2 to entry: In the framework of a product developed to satisfy a customer's need, the processes involved are the expression of the need, the establishment of the definition, the industrialization, and the production.

Note 3 to entry: The product can be either a final product to be delivered to a customer (aircraft, equipment, etc.) or one of its constituents. In both cases, it represents the supply due under the contract.

3.16
qualification of a production system
process whose objective is to demonstrate that the production system fulfils the requirements specified in the context of the realization of a product

Note 1 to entry: This qualification is based on the MIF and associated justifications.

Note 2 to entry: The qualification process is a process related to the customer or a third party appointed by the customer, where appropriate.

3.17
individual inspection register
IIR
batch inspection register
BIR
document attached to a product item (IIR) or batch (BIR) and allowing to record at least the as-built configuration of the product or batch and to pronounce acceptance

Note 1 to entry: Concerning the as-built configuration, see EN 9223-100 and EN 9223-103 relating to configuration management.

Note 2 to entry: This documented information may contain other compliance elements required by the customer.

3.18
first article critical inspection (FACI) – first article inspection (FAI) of EN 9102
planned, complete, independent, and documented inspection and verification process to ensure that prescribed production processes have produced a reproducible item compliant with the definition, cycle time related to workflows, purchase order, technical specifications, and/or other applicable design documents

Note 1 to entry: The first version of an FACI, called the initial FACI, corresponds to the production of a first part in accordance with its definition and using serial production processes.

Note 2 to entry: The FACI qualifies the production system in its production phase at the required rate of serial production.

3.19
production system
all the specific resources and technical data necessary for the supply, manufacture, assembly, integration and inspection of product constituents in accordance with applicable requirements

3.20
product validation
process which demonstrates through objective evidence (results of inspections, measurements, analysis, tests, etc.) that the product as designed fulfils the operational need in the intended operational environment

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

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

4 List of acronyms

BIR	Batch inspection register
CDR	Critical design review
DDF	Definition data file
DJD	Definition justification dossier
DJP	Definition justification plan
DMIIR	Documented manufacturing and inspection information records
E-BOM	Engineering bill of materials
ERP	Enterprise resource planning
FACI	First article critical inspection
FMECA	Failure modes, effects and criticality analysis
IADT	Inspection, analysis, demonstration and test
IF	Industrialization file
IIR	Individual inspection register
M-BOM	Manufacturing bill of materials
MI	Manufacturing and inspection
MIF	Manufacturing and inspection file
MIFC	Manufacturing and inspection flowchart
MIJF	Manufacturing and inspection justification file
MIJP	Manufacturing and inspection justification plan
MES	Manufacturing execution system
MRL	Manufacturing readiness level
MSA	Measurement systems analysis
NC	Numerical control
(N)TS	(Need) technical specification
PD	Process descriptor
PHS&T	Packaging – handling – storage – transport
PL	Product logbook
PPAP	Production part approval process
PPE	Personal protective equipment
QHSE	Quality, health, safety, environment
S-BOM	Service bill of materials
SPC	Statistical process control
WO	Work order

5 Concepts

5.1 Scope and interactions

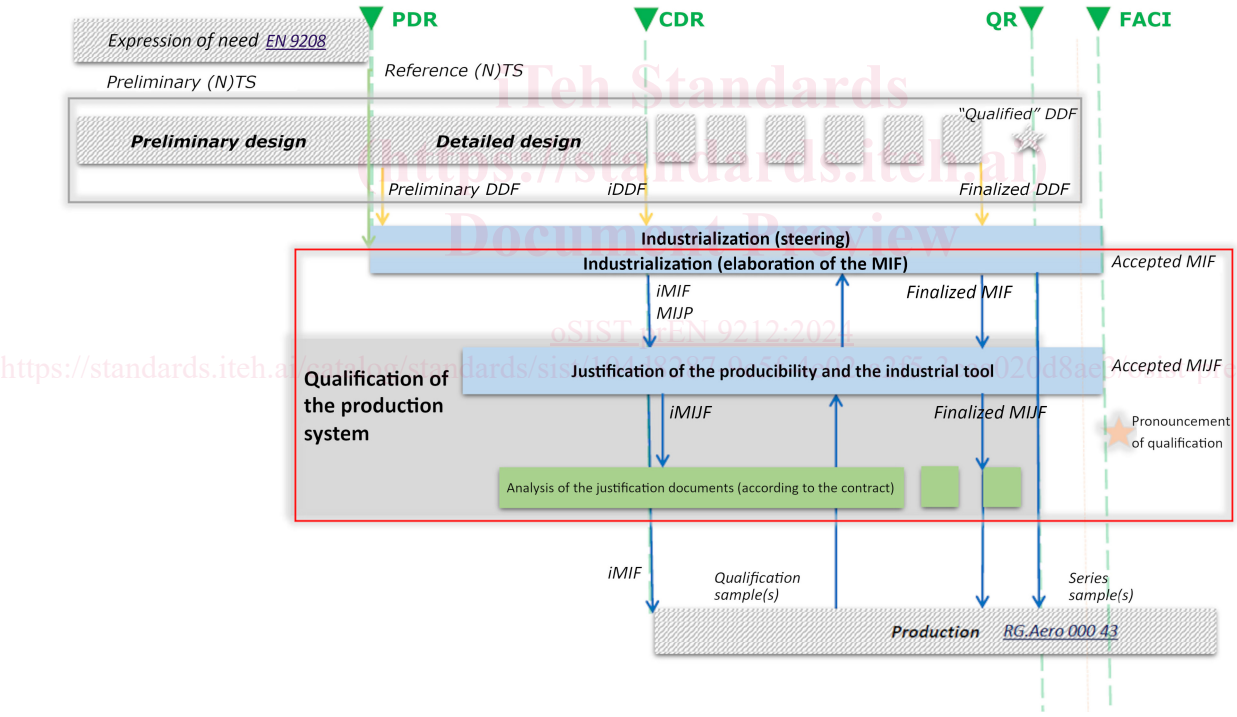
The industrialization process is closely linked to the design and production processes in order to be able to identify and take account of, at the earliest possible stage of the product definition, the requirements (contractual, regulatory authorities, etc.), the internal industrial strategies (production capacity, make or buy, etc.) and the technological constraints (performance of the means of production, compatibility of the processes, etc.).

The industrialization process begins right at the start of product design and continues as the definition data file (DDF) progresses, as part of a concurrent engineering approach.

As a general rule, the industrialization of a product is prepared and realized in parallel and consistently with the detailed design process.

For products with long procurement/manufacturing/factory assembly lead times, or for complex products, and depending on their readiness level, it may be necessary to anticipate the industrialization activities in order to meet the cost, deadline, capability, safety, performance and quality targets. The risks incurred by this anticipation need to be analysed and managed as part of the programme.

The execution logic described below (see Figure 1) shows how the industrialization and production system qualification processes interact with the development (expression of need, design, etc.) and production processes.



Key

▼	Review	iMIF/iMIJF	= intermediate
	Customer/authority responsibility		Establishment of the definition RG.Aero 000 14
	Supplier responsibility		Scope of EN 9212

Figure 1 — Processes interfaced with the industrialization process