

English Version

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

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

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

This European Standard was approved by CEN on 17 February 2025.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 9212:2025) 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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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.

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Introduction

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

This document 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.

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**

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].

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**

structured set of documents formalizing 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**

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**

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

method

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

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****batch inspection register**

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****first article inspection**

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.

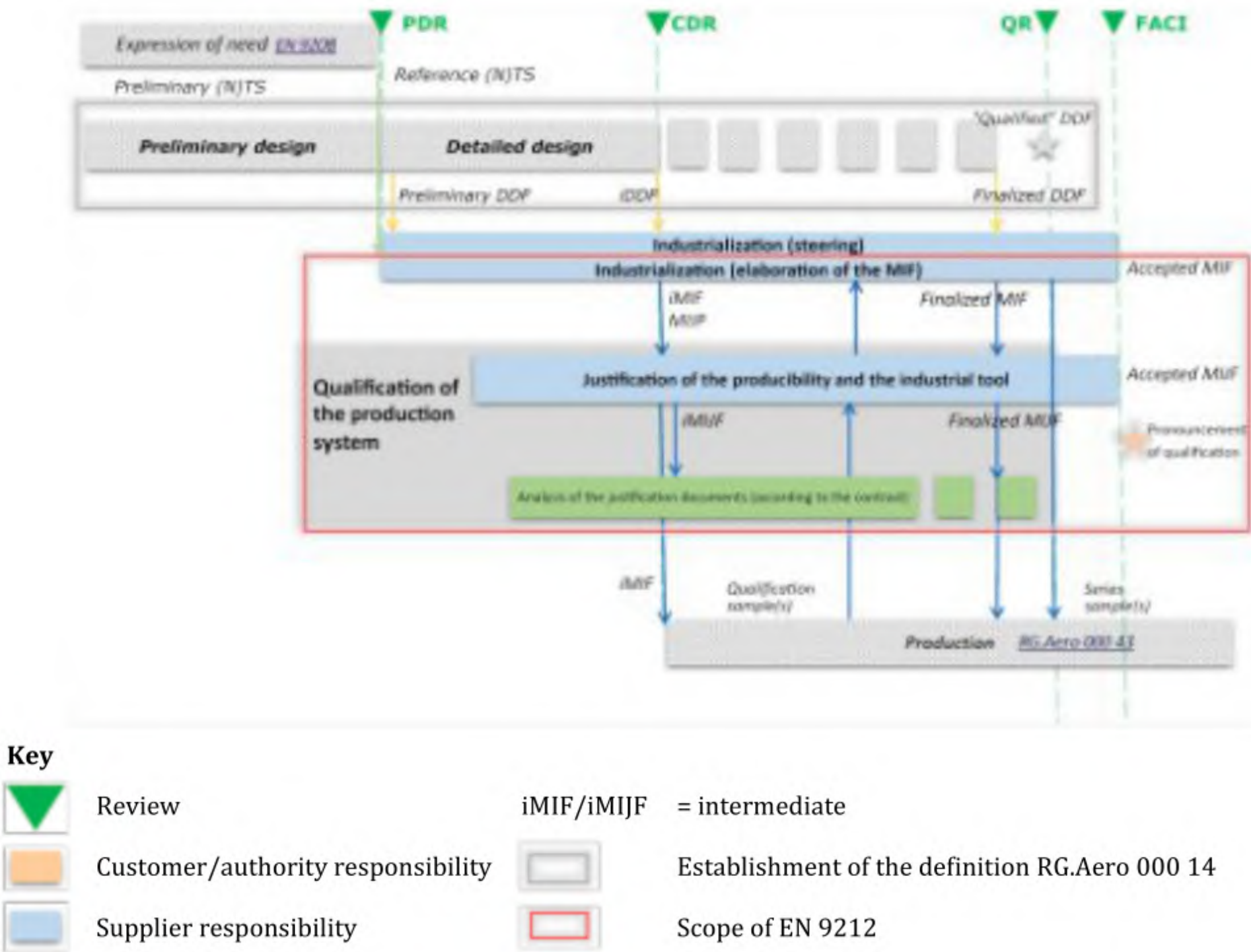


Figure 1 — Processes interfaced with the industrialization process

NOTE A “finalized” file (DDF, MIF, etc.) is a file with a status that meets the internal requirements of the organization and is submitted to the customer and/or the acceptance authority.

The industrialization process covers several aspects: the industrialization of the product itself, the elaboration of the manufacturing and inspection file (MIF), the elaboration of the associated justifications and the qualification of the production system.

The industrialization process of a product needs coordination with the product design process in terms of methods, synchronization, participants, etc. It obeys the programme management rules and takes account of the constraints and relations between the various industrialization programmes.

The MIF and the associated justifications [manufacturing and inspection justification plan (MIJP) and manufacturing and inspection justification file (MIJF)] are elaborated by the manufacturer responsible for supplying the product on the basis of the DDF (see RG.Aero 000 14).

The elements of the justifications may be analysed and validated, in part or in full, by a third party or by the manufacturer itself, depending on the contractual, regulatory or internal requirements. The qualification pronouncement, or equivalent, associated with the producibility and with the production system is the result of this analysis and validation activity.

5.2 Aim of the MIF and the justifications provided

The MIF is a result of the industrialization process, with the MIJF, which contains the results of the justification of the elements described in the MIF, on the basis of the MIJP, but also the responses to the production system qualification needs.

The aim of the MIF and its associated justifications is to guarantee the production, compliance and reproducibility of the product (in accordance with the DDF), while providing the necessary traceability with regard to the regulatory and contractual requirements.

The MIF and its associated justifications constitute the reference framework of the production process in a given industrial context (risk analysis and the associated decision making) and with objectives in terms of quality, costs, rate and lead times (cycles), capability and safety.

5.3 Structure of the documented information

The MIF and its associated justifications contain all the associated information on the product realized with regard to the DDF.

The identification of the MIF should contain the identification of the product.

Depending on the organization of the company, the contractual requirements and the constraints applying to the realized products, the MIF and its associated justifications may be structured into different parts in order to meet the various external or internal demands more easily. This approach ensures that only the necessary information is sent to the customer.

NOTE In this case, the goal consists of conserving the knowledge and know-how of the supplier, which can be open to audit by the customer, but not transmissible.

For each item of documented information, this structure can be used to define the expected objective, which is characterized by a type file.

EXAMPLE These type files include: the installation and inspection file (IIF) or assembly and inspection file (AIF), the installation and inspection justification file (IIJF) or assembly and inspection justification file (AIJF), the manufacturing choices justification file (MIJF), the installation choices justification file (ICJF) or the assembly choices justification file (ACJF), etc.

The associated justifications may be delivered to an inspection authority or the customer, in accordance with the terms of the contract.

5.4 Impacted stakeholders in the organization

Figure 2 shows an example of a representation of all the stakeholders involved in the industrialization process, and in particular in the elaboration of the constituent elements of the MIF and its associated justifications.

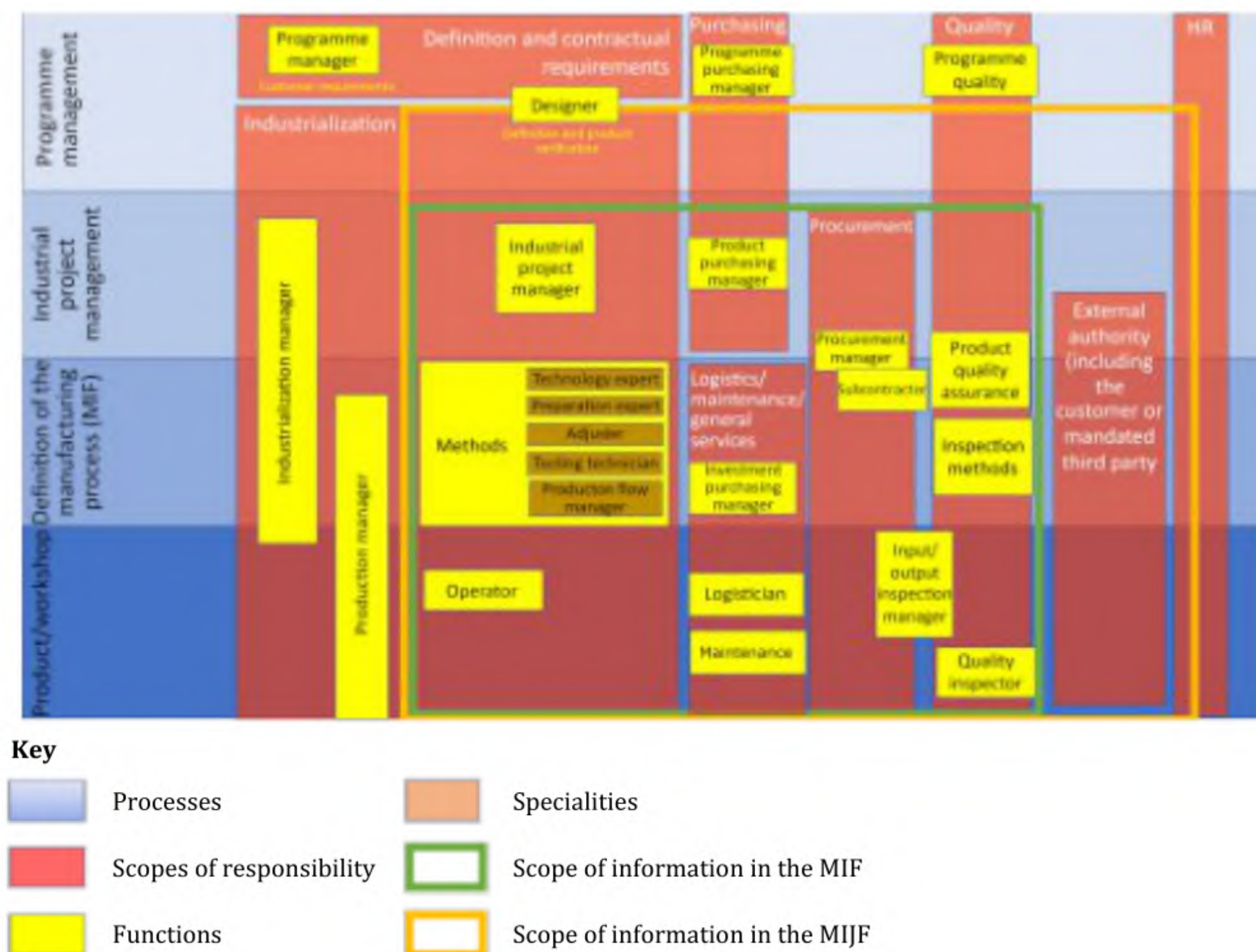


Figure 2 — Map of the stakeholders that contribute to the industrialization process

5.5 Recipients of the MIF and the associated justifications

The MIF (in part or in full) is intended for:

- production planners, for the aspects related to the operating procedure;
- procurement/purchasing, because it characterizes the raw materials, constituents and subcontracted products;
- workshop operators, in order to apply the implementing provisions for the manufacturing, inspection or test operations;
- production support departments (methods, maintenance, quality, etc.), in order to implement the provisions for controlling and/or monitoring processes, tooling and means of testing and production;
- the organization's quality department, because it contains the necessary information for the various reviews and to control the activities.

It could be made available for the customer for consultation, according to the terms of the contract.

The associated justifications (in part or in full) are intended for:

- the customer, when it is a contractual requirement;
- the organization itself, when required by the organization's internal procedures, in particular as proof during technical events, proof of the initial first article critical inspection (initial FACI), etc.;
- the regulatory authorities (pyrotechnical safety, electrical safety, confidentiality, etc.).

The conditions applying to the disclosure of manufacturing and inspection data may be subject to special contractual provisions (intellectual property, know-how or other regulatory restrictions, etc.). The customer and the supplier reach an agreement on a selection of data that is necessary and sufficient to exercise their activities, and, in this regard, the contract specifies the information to be exchanged and the modes of access.

6 Elaboration process of the MIF and the associated justifications

6.1 Data to be taken into account

In order to be able to carry out the MIF and the associated justifications elaboration process, it is necessary to perform a precise analysis of the following input data:

- the DDF (technical constraints, imposed processes, results of the product FMECA, the key characteristics, etc.);
- the requirements of the (need) technical specification [(N)TS] of the customer related to producibility and reproducibility (control of the production system);
- programme-related requirements (rates, management plan, contractual and regulatory obligations, technical specifications and standards, costs, requirements related to the quality management system, configuration management, etc.);
- strategy and industrial constraints:
 - o lessons learned from the preceding industrializations (know-how of the company);
 - o taking into account of the constraints and relations with other industrialization programmes in progress (inspection of common resources, etc.);
 - o means, skills, methods, instructions and procedures, manufacturing and inspection facilities and tooling, etc.;
 - o manufacturing readiness level (MRL) and control of the manufacturing processes to be implemented;
 - o capability to maintain the production system in an operational condition;
- procurement strategy and constraints, suppliers and available means (imposed suppliers, single-sourcing, obsolescence management, export control, etc.);
- regulatory constraints pertaining to security, safety, the environment, health, etc.

The relative importance of each item of input data varies according to the kind of product.

6.2 Position in the execution logic

The elaboration logic of the MIF and its associated justifications needs programme-wide synchronization that is consistent with the elaboration of the DDF at its different maturity levels [linked to the milestones of the execution plan (see RG.Aero 000 41)]. This logic allows a gradual construction of the demonstration of the producibility and reproducibility, between what is planned (DDF) and what is realized (physical output of the MIF), while taking account of the enablers (production system, support system) and the necessary stakeholders points of view of the that take part in the activities.

NOTE For details of the support system aspects, see RG.Aero 000 76.

This approach is incorporated in the various phases of the industrialization logic (Figure 3).

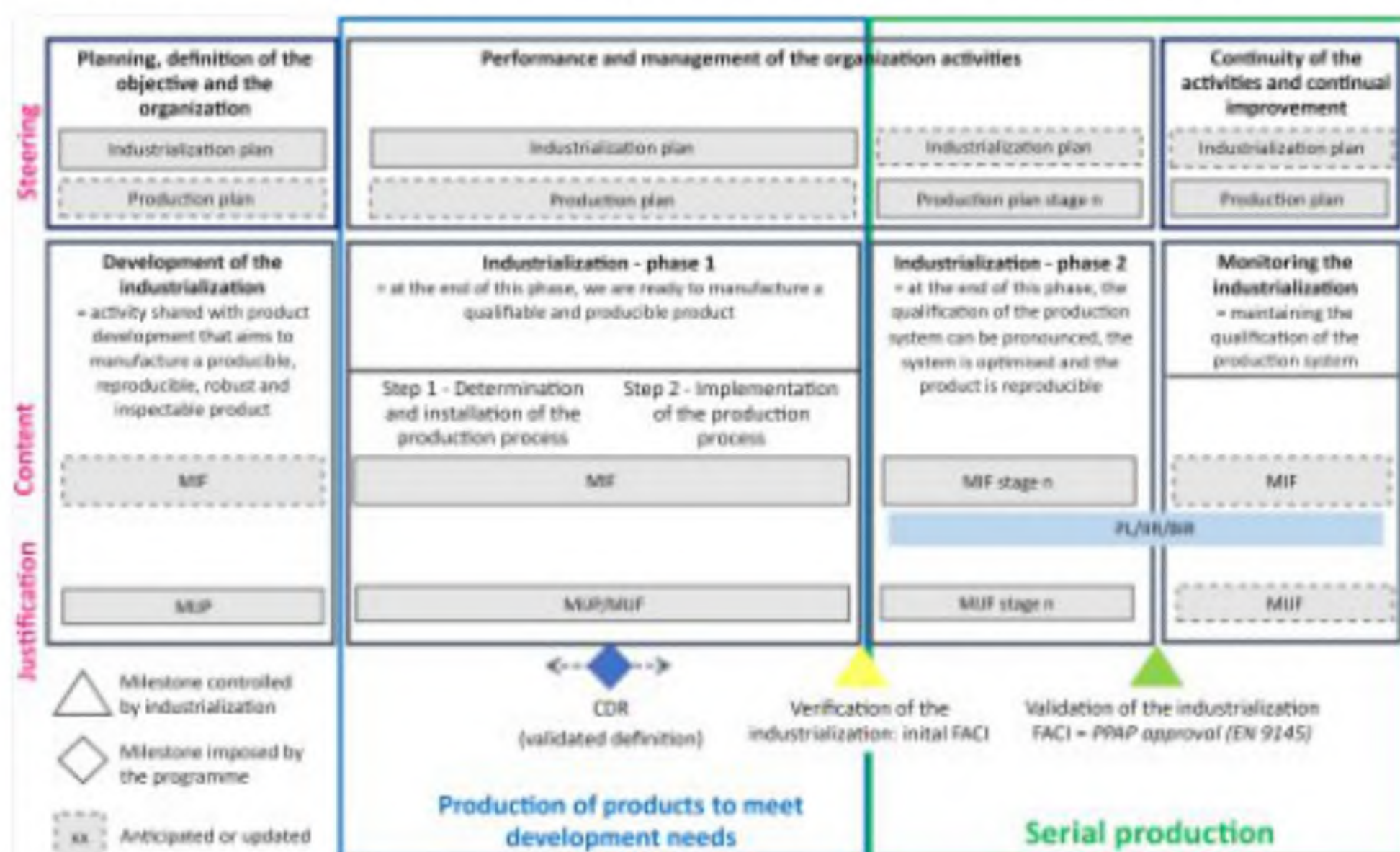


Figure 3 — Industrialization logic

The industrialization logic follows an iterative approach that is structured in phases and steps corresponding to the expected MRLs:

- during the development of the industrialization, co-engineering (design/industrialization) enables the industrial means of the production system to be deployed to be specified and planned;
- in phase 1 – step 1, the procurement of the means of production, the deployment and adjustment of the production system, as the taking into account of the associated support system requirements (including training), are realized. At the end of this period, the DDF of the product is imperatively validated and the production system can demonstrate producibility;

NOTE Long procurement lead times can be initiated at the end of step 1.

- in phase 1 – step 2, samples are manufactured using processes representative of the serial production processes. This realization allows to validate the producibility of the product and the capability of the production system and the associated support system to realize the product;
- in phase 2, the serial production of the product is launched (reproducible product). The optimization of the production system and its support system is sought in order to achieve the expected production objectives;
- the last phase, during serial production, allows to ensure the maintenance and continual improvement of the production system.

This elaboration is validated in successive reviews of the constituent elements of the MIF.

6.3 Improvement logic of the MIF

The following flowchart (Figure 4) shows the various steps of the elaboration of the MIF and its associated justifications, from its initialization to its validation.

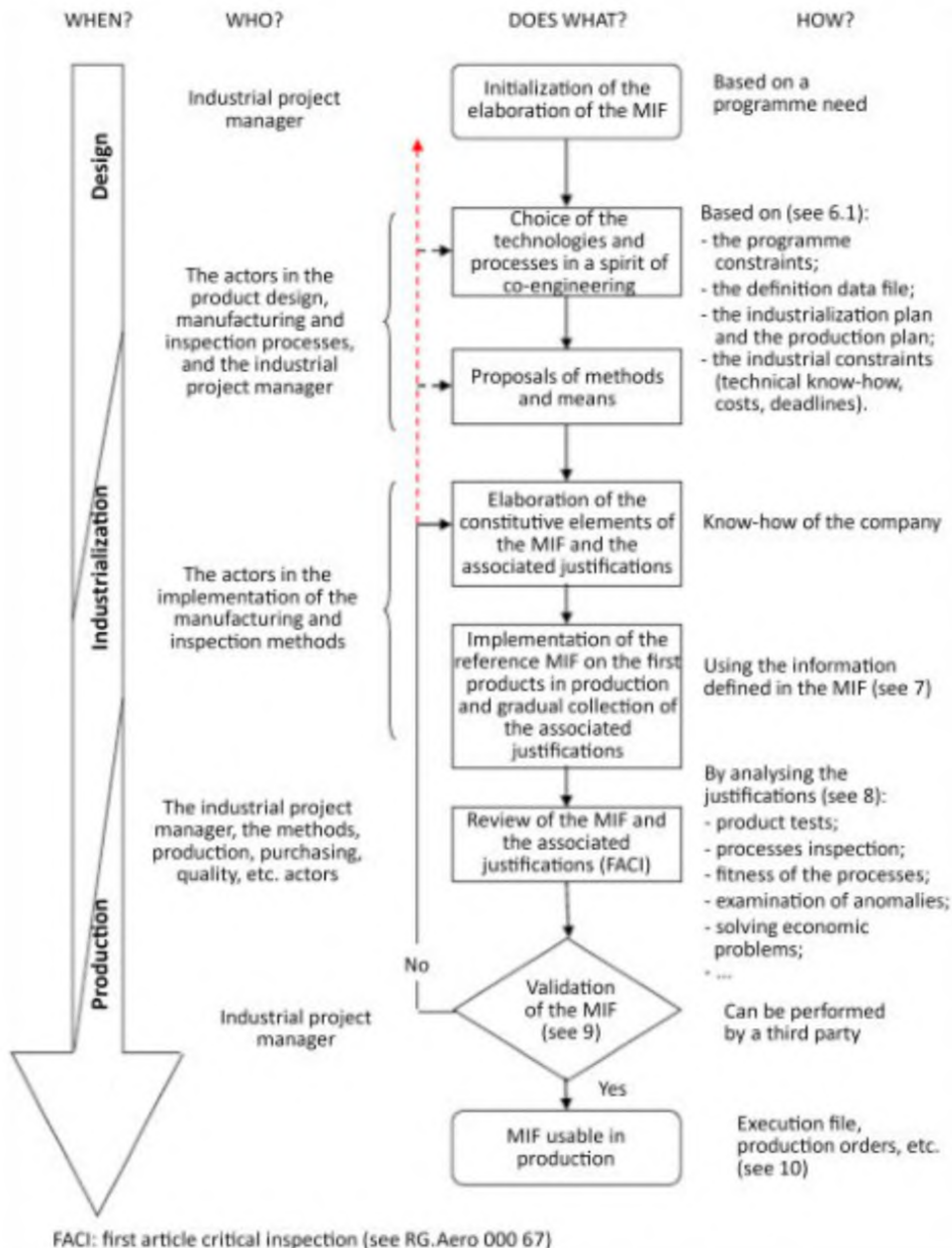


Figure 4 — Elaboration process for the MIF — Project perspective

The elaboration logic of the MIF and its associated justifications follow the industrialization logic. Consequently, it is necessary to structure three aspects of the elaboration logic of the MIF:

- the strategy to be implemented: this first aspect related to steering needs the elaboration of an industrialization plan that provides to all the resources working on the programme a coherent vision of the necessary synchronization between the DDF, the MIF and the MIJF, and also between the production activities. The definition of this implemented strategy is in general formally laid down in an industrialization plan. The production plan (see RG.Aero 000 43) is usually launched in parallel, in order to guarantee industrialization/production consistency. This strategy is updated and fine-tuned during the phases/steps of the industrialization logic. The industrialization and/or production plans are updated during the design phase in order to take account of design-related events;
- the elements linked to the content of the MIF: this second aspect is related to the content of the MIF and is built gradually, directly in line with the readiness level maturity of the various versions of the DDF and the aspects related to the production system. This logic is described in 6.3;
- the justification elements of the MIF: this third aspect is related to the content of the MIJP and the MIJF, which are prepared in parallel, and its construction is directly related to the maturity of the various versions of the MIF.

In order to control each production elementary process, a file is established at each level of the production breakdown structure where a constituent part is to be realized by taking account of the interfaces.

7 Content of the MIF

7.1 Global overview of the MIF

Figure 5 shows a typical breakdown structure of the constitutive elements of an MIF, which are described in detail in the following paragraphs. In addition to the hierarchical links, transverse interactions exist between each element.

This typical breakdown structure is designed at a given article level (industrial scope), in correlation with the breakdown structure of the DDF and according to the complexity of the product, the contractual terms, etc.

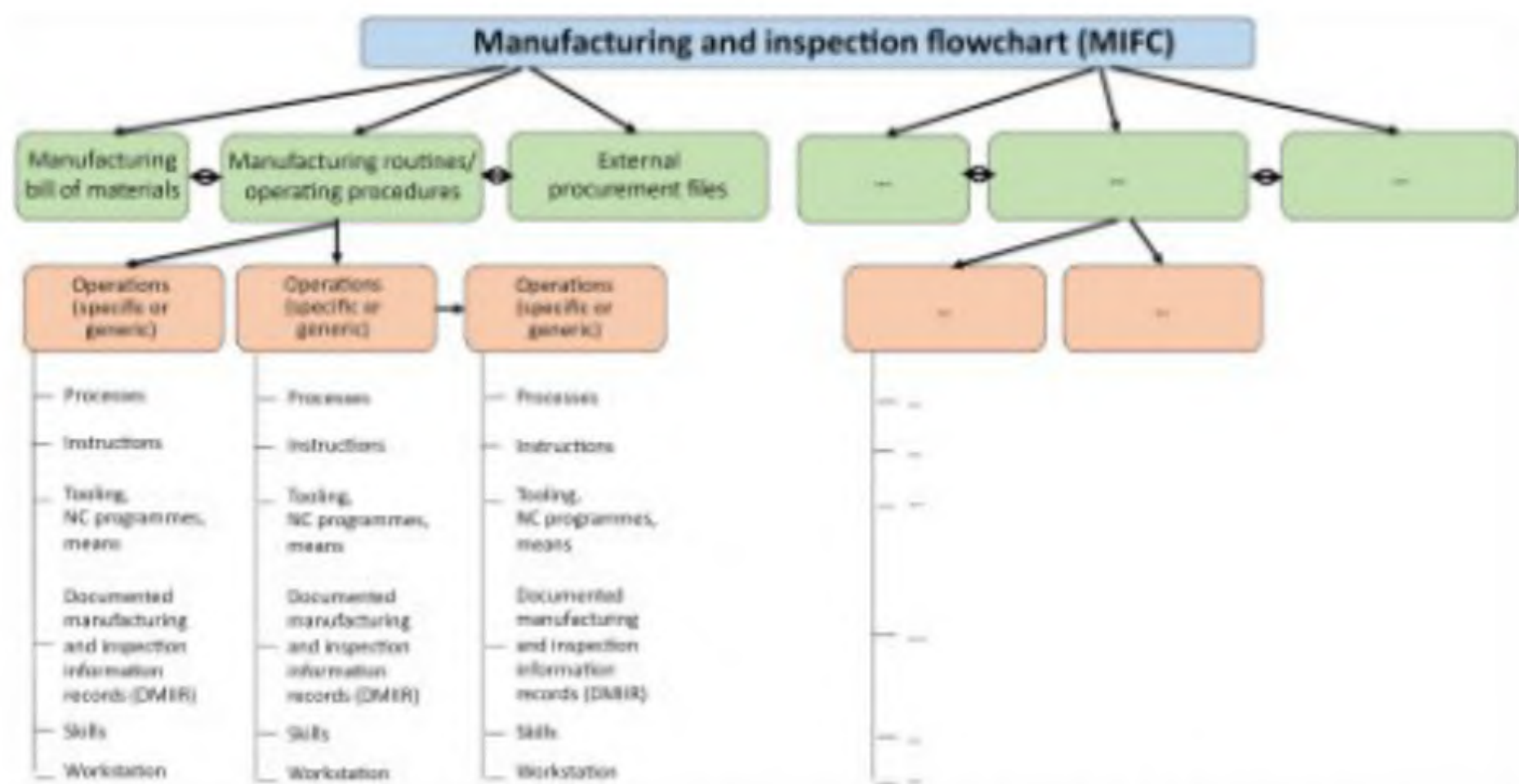


Figure 5 — Typical breakdown structure of the elements of the MIF

The complexity of the constitutive elements of the MIF and its justifications may vary, depending on the kind of product in question, on the one hand, and on the stage of elaboration of the product (development, pre-series or serial production) on the other.

The content of the MIF takes account of “functions” lessons learned and of the structure of the available information systems.

7.2 Detailed composition of the MIF

7.2.1 Manufacturing and inspection flowchart (MIFC)

The MIFC (see Table 1) is a graphic breakdown of the DDF from the perspective of industrialization that is used to share and collectively understand the cycle of the product production process in order to make sure that the contractual requirements are taken into account correctly.

Table 1 — Manufacturing and inspection flowchart

<p>Aim: The MIFC materializes the manufacturer's (industrialization team) thinking on the optimized sequence of the manufacturing and inspection steps, for a given level of production, in response to the various requirements.</p>	<p>Owner: Industrialization manager</p>	<p>Users: Methods Quality assurance Procurement manager Designer</p>
<p>Input and opportunities: <u>Technical data:</u> <ul style="list-style-type: none"> product DDF: design office/design authority; industrial requirements (production costs, reliability, cycle, constraints of the production scheme): programme team; industrial policy: company (make or buy, internal standard, purchasing policy, quality policy, etc.); normative (e.g. special processes) and regulatory environment; contractual requirements: customer demands (e.g. industrial scheme). <u>Opportunities:</u> contextual parameters/industrial environment (partnerships, etc.).</p>		
<p>Transformations: Following the thinking of the industrialization (compromise between requirements/capacities), the MIFC allows to view the optimized sequence of the manufacturing steps (meeting the cost, quality and deadline objectives). It allows to validate the consistency with the DDF, in particular with regard to the checkpoints and forms a link between the definition and the chosen manufacturing process. In the event of subcontracting, it constitutes fundamental input data for the teams in order to break down the requirements in the associated documents.</p>		
<p>Output and interfaces: Flowchart that specifies the following for the different realization teams: <ul style="list-style-type: none"> the chronology of the manufacturing steps with the references of the main documents, if necessary; the logic of the steps and the characteristics (including the key characteristics) of the associated internal/external inspections; all the critical information on the sustainability of this manufacturing process. And it also includes, in the MIFC or an associated document: <ul style="list-style-type: none"> the "industrial breakdown" and the production breakdown structure (make or buy, imposed suppliers, etc.), including the configuration items and the parameters (key characteristics, for example). </p>		
<p>Formalization: In the form of a "standardized" chronological synoptic/flowchart, with symbolic representations of the manufacturing steps and the checkpoints/self-checks. This synoptic can be broken down into several levels or several scopes, while totally covering the product.</p>		
<p>Best practices: <ul style="list-style-type: none"> it is produced together with the MIJP: it is implemented right from the detailed design phase as part of the co-engineering process (managed during the successive project reviews): entry point of the IF; it forms the link between production and the design offices (it is used as a link to manage reciprocal impacts in the event of changes); it is elaborated collaboratively by the various methods departments and forms part of the IF; it is elaborated in accordance with the definition breakdown structure, in particular for technical change management aims, while also taking the industrial constraints into account; validation is reached during the co-signatory final industrial validation, e.g.: manufacturer, quality, designer, RAMS; it is requested from subcontractors; it is maintained when a change (in the definition, technical, organizational, etc.) so requires, as part of the updating of the MIF; in cases of multiple sources, there are several MIFCs. At the start of industrialization, it is the risk analysis that identifies the processes to be monitored particularly closely in order to realize the product (key characteristics, etc.). The level of detail and formalization of the MIFC is defined according to the complexity of the process, the customer's requirements, etc. It may be limited to the manufacturing routine. By way of example, RC.Aero 003 40 may be consulted.</p>		

7.2.2 Manufacturing bill of materials (M-BOM)

The elements to be taken into account are identified in Table 2 below:

Table 2 — Manufacturing bill of materials

<p><u>Aim:</u> List of the made or bought items that describes the compound/constituent relations corresponding to the stages of elaboration of the product. It is established in accordance with the engineering bill of materials (E-BOM).</p>	<p><u>Owner:</u> Methods</p>	<p><u>Users:</u> Procurement manager Production flow manager Operator Inspector</p>
<p><u>Input and opportunities:</u></p> <ul style="list-style-type: none"> • DDF; • technical procurement data; • support definition specification; • delivery status; • quality instructions; • list of industrial means, tooling and consumables; • MIFC, including the industrial breakdown structure (make or buy). 		
<p><u>Transformations:</u></p> <p>It takes the production logic step by step to draw up the list of necessary and sufficient quantities of items required to produce, with the necessary characteristics (part number, standard, item code, etc.).</p> <p>The means and tooling to be used in the product production process are included in the list of means and tooling of the manufacturing bill of materials and are referenced to in the manufacturing routine or in the operating instruction in the phase where they shall be used.</p>		
<p><u>Output:</u></p> <ul style="list-style-type: none"> • list of the constituent parts from the E-BOM, completed by items from the production needs. The breakdown structures may be adapted to the industrial context; • elements used to produce the S-BOM (structure of the services associated with the product, including maintenance). 		
<p><u>Formalization:</u></p> <ul style="list-style-type: none"> • documented M-BOM in the information system of the production system. 		
<p><u>Best practices:</u></p> <p>When several variants are acceptable in the design, the M-BOM allows to select the item required to manufacture the end product.</p> <p>In cases of long and complex assembly, the M-BOM is based on the assembly logic.</p> <p>In the product development phase, an E-BOM breakdown structure is built that corresponds to the needs of the M-BOM breakdown structure, in order to facilitate checks of completeness between the M-BOM and the E-BOM.</p> <p>As far as is possible, the M-BOM takes account of considerations related to support (S-BOM).</p>		

NOTE An example of the transformation of an E-BoM into a M-BOM according to the industrial organization is provided in Annex D for reference.

7.2.3 Manufacturing and inspection routine (or manufacturing and inspection operating instruction)

The elements to be taken into account are identified in Table 3 below:

Table 3 — Manufacturing and inspection routine

<p><u>Aim:</u> The routine is intended to manage production flows in serial production.</p> <p>The routine is used to chronologically plan, structure and document the manufacturing and inspection operations (machining, assembly, tests, trials, etc.) to be done to obtain the expected product.</p> <p>NOTE The elements of 7.2.3 are applicable for an internal or outsourced realization.</p>	<p><u>Owner:</u></p> <p>Methods (preparation expert)</p>	<p><u>Users:</u></p> <p>Production flow manager</p> <p>Procurement/subcontracting manager</p> <p>Quality inspector</p>
<p><u>Input:</u></p> <ul style="list-style-type: none">• MIFC;• bill of materials;• DDF;• workstations;• procurement data;• industrial requirements (programme, project, contract, industrial);• industrial policy (internal directives, including configuration control);• existing infrastructures and logistics of the production unit;• technical readiness of the processes;• economic data;• information system.		
<p><u>Transformations:</u></p> <p>Manufacturing and inspection routine documents at least the following:</p> <ul style="list-style-type: none">• all the necessary manufacturing, inspection, testing, logistics, etc. operations in chronological order;• the technical and administrative characteristics of the different operations, and in particular the manufacturing costs and lead times (with the sizing of the production batches, if necessary);• the configuration control data, including traceability, in accordance with the applicable requirements (version, description of changes, approver, etc.). <p>Manufacturing routine covers all (single-routine MIFC) or a part (multi-routines MIFC) of the scope of the MIFC.</p> <p>The routine may include outsourced operations.</p>		
<p><u>Output and interfaces:</u></p> <p><u>Output:</u></p> <ul style="list-style-type: none">• list of the scheduled operations;• manufacturing cycle;• operational time allocation.	<p><u>Interfaces:</u></p> <ul style="list-style-type: none">• quality;• external authorities;• flow management;• procurement manager.	
<p><u>Formalization:</u></p> <ul style="list-style-type: none">• hardcopy or electronic document;• information system;• flowchart.		
<p><u>Best practices:</u></p> <p>The routine is to be defined at the earliest possible stage, in collaboration with product design (co-engineering) in order to obtain a producible and reproducible definition.</p> <p>The routine is to be applied to the industrial means of serial production at the earliest possible stage.</p> <p>In cases of multi-routines, it is necessary to establish the consistency/interfaces between the routine.</p> <p>The entire routine is to be validated as soon as all the operations are complete. In cases of subcontracted operations (internally or externally), the control of the routine belongs to the production entity that adds the most value to the product.</p>		

7.2.4 External procurement file

The elements to be taken into account are identified in Table 4 below:

Table 4 — External procurement file

<u>Aim:</u> To obtain the necessary information to:	<u>Owner:</u>	<u>Users:</u>
<ul style="list-style-type: none">• order services or operations from a subcontractor for a clearly stated reason (know-how, workload/offloading, means to be implemented, space, location, etc.);• gain access to equipment and/or raw materials and/or services;• keep track of the ordered activities and deliverables.	Procurement manager	Subcontractor Purchaser
<u>Input:</u> <ul style="list-style-type: none">• DDF;• list of imposed supplies;• structure of the MIF, MIJP and MIJF;• MIFC (formalization of the data flows);• purchasing process;• purchasing/procurement policy;• provisional procurement plan.	<u>Opportunities:</u> <ul style="list-style-type: none">• secure and facilitate the consolidation of the subcontractor's documented information.	
<u>Transformations:</u> <ul style="list-style-type: none">• perform the identified activities in order to deliver the expected result to the requesting party through the procurement file:<ul style="list-style-type: none">• either extracted directly from the DDF, when the procured product is not transformed (e.g. electronic components, equipment);• or deduced from the DDF in the elaboration of the routine, when the procured product shall be transformed (e.g. raw materials and semi-finished products);• conduct intermediate inspections and procure the necessary raw materials;• check the result prior to validation by the requesting party in order to continue the planned activities;• implement the necessary processes (internal procurement, logistics, definition, industrialization, production, tests, etc.).		
<u>Output and interfaces:</u> The procurement file, which contains: For the subcontracting of production <ul style="list-style-type: none">• (Need) technical specification (see EN 9208) or delivery technical specification (including the definition);• logistical requirements (PHS&T);• quality requirements to be met by the supplier;• order (contractual and financial conditions, administrative and regulatory rules); etc.); • acceptance file/receipt inspection.	Potential additional information in cases of the subcontracting of industrialization and production <ul style="list-style-type: none">• programme management specification (see EN 9200);• detailed composition of the services;• safety and non-disclosure clauses;• acceptance specifications/DJP;• list of the interfaced systems/equipment and data exchange format;• supplier FACI;• required parts of the MIF (MIFC,• list of the applicable documents;• etc.	<u>Interfaces:</u> <ul style="list-style-type: none">• industrialization;• production;• quality;• purchasing;• programme;• design authority;• legal oversight authority.
<u>Formalization:</u> <ul style="list-style-type: none">• external procurement file (in keeping with the company's practices).		
<u>Best practices:</u> <ul style="list-style-type: none">• send the necessary information to the subcontractor only with a confidentiality check;• oversee, without intervening, the subcontractor's processes (interference);• include the subcontractor at the earliest possible stage;• the procurement officer coordinates the major cross-functional actors who are impacted (product manager, work package manager, project purchasing leader, project quality, inspection, etc.) and defines their respective responsibilities.		

7.2.5 Operations

An operation is a part of the routine. The elements to be taken into account are identified in Table 5 below:

Table 5 — Operations

<p><u>Aim:</u> The operation formally defines the activity to be performed (transformation of the part, inspection, etc.) within the framework of a workstation and pre-determined human or material resources.</p> <p>The chronological sequence of the operations forms the manufacturing routine/operating instruction.</p> <p>An operation can be outsourced to the production entity concerned (subcontracting of routine to another production entity or an external service provider).</p>	<p><u>Owner:</u></p> <p>Methods (preparation expert)</p>	<p><u>Users:</u></p> <p>Operator Quality inspector External authority (in the event of external subcontracting)</p>
<p><u>Input:</u></p> <p><u>Data characterizing the operation:</u></p> <ul style="list-style-type: none">• processes;• instructions;• tooling, NC programmes, means;• skills;• workstation;• documented MI information.	<p><u>Additional data:</u></p> <ul style="list-style-type: none">• MIFC/routine;• items in the M-BOM necessary for the operation (constituents, materials, etc.);• product characteristics (drawings, status after operation n-1);• industrial constraints;• applicable technical specifications (DDF);• QHSE standards including people's health and safety aspects.	
<p><u>Transformations (use):</u></p> <p>An operation is characterized by:</p> <ul style="list-style-type: none">• an identifier: operation number or reference;• a functional designation (related to the workstation);• the scheduled productivity data (set-up time, execution time, production rate, passage time, etc.);• the information necessary for the operation, taken from the input data characterizing the operation. <p>Depending on the complexity of the operation, the above characteristics can be documented directly in the text of the operation or included in adapted instructions.</p>		
<p><u>Output:</u> a documented operation in accordance with the provisions of the organization (with the complete list of necessary input, including the operational time allocations, unless specified in the routine) and consistent with the adjacent operations.</p>		
<p><u>Formalization:</u></p> <ul style="list-style-type: none">• production information system [manufacturing execution system (MES)/enterprise resource planning (ERP)];• hardcopy documents or other electronic media.		
<p><u>Best practices:</u></p> <ul style="list-style-type: none">• the elaboration of the operation is usually initiated on the basis of existing operations by incorporating lessons learned and the new requirements associated with the product/workstation;• in the description of the operation, generic instructions are preferred to specific instructions;• an operation can be broken down into sub-operations or phases, depending on the complexity of the work/the added value to be created and the organization of the workstation;• it is recommended, before performing an operation, to associate the characteristics of the operator's skills and the metrology systems to check their validity during the execution of the operation;• highlight the operation when it involves special processes or processes that need particularly close monitoring;• when an operation is optional, clearly explain the cases where it need not be carried out and the criteria used to justify it.		

7.2.6 Processes

A process is a part of the operation. Elements are identified in Table 6 below:

Table 6 — Processes

<p>Aim: A process is a transformation method that, when used together with equipment and skills, is intended to perform a manufacturing or inspection activity on a product in a given environment.</p> <p>A process is defined and controlled independently of the product and the upstream and downstream processes.</p> <p>A process is a way of giving the material the desired state and characteristics by implementing, under the defined conditions, a set of pre-established means and methods.</p> <p>A process can be characterized by the 5Ms (method, mother nature (environment), means, material, manpower).</p> <p>Special process: any process whose results cannot be entirely and/or immediately verified by an inspection and/or a non-destructive test of the product and in which, for example, the deficiencies of the process may only appear once the product is in use.</p> <p>NOTE The implementation of certain processes can incur risks and require specific means of control, in keeping with the internal provisions of the organization and the contractual requirements.</p>	<p>Owners:</p> <p>Industrialization (for processes to be developed)</p> <p>Production (for existing processes)</p>	<p>Users:</p> <p>Industrialization</p> <p>Manufacturing</p> <p>Inspection</p>
<p>Input:</p> <ul style="list-style-type: none">• verification criteria of the 5Ms;• use case or definition data;• requirements (for implementation and maintenance, qualification and monitoring of the process, legal requirements, etc.);	<ul style="list-style-type: none">• means (industrial tools);• consumables, ingredients, constituents;• skills and operators;• lessons learned (capacity, maturity/MRL, etc.).	
<p>Transformations:</p> <p>Transformation step/controlled added value of the product:</p> <ul style="list-style-type: none">• definition of the specifications;• achievement of the required MRL;• economic analysis;	<ul style="list-style-type: none">• technological adjustment;• FMECA;• engineering calls for tender.	
<p>Output and interfaces:</p> <p>Output:</p> <ul style="list-style-type: none">• manufacturing and inspection means (including generic tooling); process monitoring plan and records templates;• list of additional means;• characterization of the necessary skills;• generic instructions/workstation instructions, safety;• process qualification.	<p>Interfaces:</p> <ul style="list-style-type: none">• 5M;• operations;• workstation;• instruction;• skills;• tooling• documented information.	
<p>Formalization:</p> <ul style="list-style-type: none">• description of the process;• industrial organization.		
<p>Best practices:</p> <ul style="list-style-type: none">• make use of the requirements/inspections that guarantee the control of the process (process authorization, authorization/certification of the personnel) in an ERP, wherever possible;• creation of a process description (PD): e.g. a document containing the following information for every production process:<ul style="list-style-type: none">• process definition;• associated monitoring parameters;• purpose and scope;• materials;• means;• mother nature/environment;• manpower;• method;• required information;• required tooling;• quality, environment, safety;• to improve the robustness of the processes:<ul style="list-style-type: none">• implement of statistical process control and guarantee the capability of the process in relation to the process parameters;• realization of process FMECA;• implement of experience plans (e.g. Taguchi method). <p>The qualification of a process is a key step for its use in serial production in the long term. The process qualification plan is adapted to the technological readiness level, the control of influential parameters, the ability to measure the results achieved, etc. It is necessary to manage the processes changes in order to control the impacts (including non-regression in the use</p>		

7.2.7 Instruction

An instruction is a part of the operation. The elements to be taken into account are identified in Table 7 below:

Table 7 — Instructions

<p>Aim: Documented information describing a production operation, the operating process and the manufacturing and inspection criteria necessary to perform the production operation in accordance with the requirements and in a reproducible way.</p> <p>An instruction may be generic (defining a production step that may be applied to several products) or specific to one product.</p> <p>An instruction shall be clear and understandable by the user.</p>	<p>Owner:</p> <p>Methods</p>	<p>Users:</p> <p>Persons tasked with performing the manufacturing operation (operators, technicians, etc.) and/or inspection operation.</p>
<p>Input:</p> <p><u>Input (for generic instruction):</u></p> <ul style="list-style-type: none">• technical specifications of the validated process (company standard, customer standard, other standards, etc.);• workstation;• means of production and/or inspection;• necessary PPE;• traceability records needed;• quality management system;• documentation of the suppliers of the means of production, raw materials, constituents, consumables, etc.;	<ul style="list-style-type: none">• available human resources and skills;• criticality of the operation;• lessons learned;• process FMECA. <p><u>Additional input (for specific instruction):</u></p> <ul style="list-style-type: none">• DDF;• manufacturing routine;• inspection plan.	
<p>Transformations:</p> <p>An instruction defines or refers to at least the following items, which are necessary to perform the production step:</p> <ul style="list-style-type: none">• the standard modus operandi of the manufacturing or inspection process;• the criticality of the process (in particular for special processes);• the analysis of the context (human factor, etc.);• the means of production, tooling and/or computer programmes;• the instructions for PHS&T and marking; <p>Each instruction is identified and included in the company’s configuration management system. Changes shall be validated by a competent authority.</p>	<ul style="list-style-type: none">• the workstation;• raw materials, consumables, constituents or subsystems;• the conditions/criteria necessary to perform the production step in order to guarantee the compliance of the product (traceability, periodical inspections, etc.);• the first-level maintenance to be performed.	
<p>Output:</p> <ul style="list-style-type: none">• manufacturing and inspection instruction;• training plan, if necessary.		
<p>Formalization:</p> <ul style="list-style-type: none">• production information system (MES/ERP);• hardcopy documents or other electronic media.		
<p>Best practices:</p> <p>Illustrate the operating process/task with photos, images, diagrams and videos.</p> <p>Create and update the instructions during the production phase (addition to a “fault library”, etc.), in particular by making use of non-conformances or technical events, with the special remarks of the operators/technicians who use these instructions (lessons learned). Reviews may be organized to collect the lessons learned.</p> <p>The instructions may mention the periodical inspections of the means, processes and products, and any particular precautions.</p> <p>The level of detail of the instruction may vary according to the criticality of the process.</p> <p>Avoid the multiplication of specific instructions in favour of generic instructions and capitalize information and best practices relating to the process.</p> <p>The procedures of the functional tests and final inspection of the product, the key point inspection procedures prior to delivery, the packaging and transport procedures are included in the MIF.</p>		

7.2.8 Associated tooling, means and computer programmes

7.2.8.1 Definitions

Generic means: set of physical means that is not specific to a product (machine tools, handling systems, three-dimensional measuring machines, infrastructure, etc.).

Specific means: set of physical means that is specific to one or more products and is defined by the specifications dedicated to this or these products (special machines, test benches, assembly jigs, etc.).

The means contribute to the definition of the workstation.

Specific tooling: specific equipment (or software) dedicated to one or more products that is used to manufacture and inspect the parts (dies, numerical control programmes, harnesses, etc.), defined by specifications and used as an interface/link between generic or specific means and a product.

Standard tooling/tool: commercial-off-the-shelf equipment (or software) used to perform operations on the product and that need not be dedicated to a workstation.

The configuration of specific means and specific tooling is managed according to the configuration of the product.

Figure 6 sets out the positions of the various means and tooling:

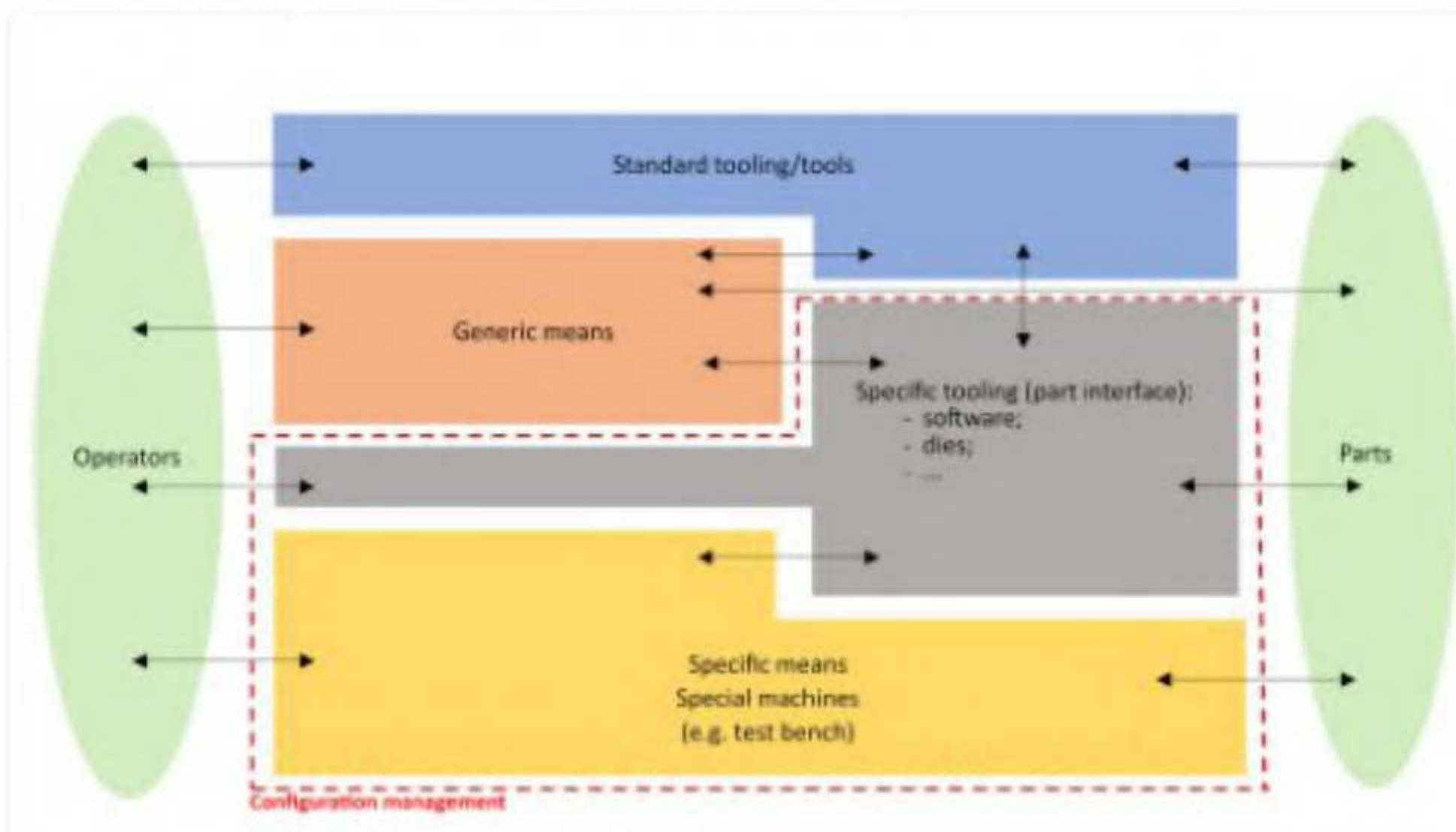


Figure 6 — Specific or generic tools, tooling and means

The boundary between means and tooling may vary according to the industrial organization.

7.2.8.2 Elements to be taken into account

Tools are a part of the operation. The elements to be taken into account are identified in Table 8 below:

Table 8 — Tools

<p><u>Aim:</u> To prepare and perform a manufacturing and/or inspection operation.</p>	<p><u>Owners:</u></p> <p>Industrialization/ methods (creation, modification)</p> <p>Production (use)</p>	<p><u>Users:</u></p> <p>Persons tasked with performing the manufacturing (operators, technicians, etc.) and/or inspection operation.</p> <p>Maintenance</p>
<p><u>Input:</u></p> <ul style="list-style-type: none"> • definition of the standard part and/or the standard process; • existing means and tooling; • industrial requirements of the contract; • legal and regulatory requirements; • MIFC/operating instruction/industrialization engineering; • physical constraints; • industrial strategy. 		
<p><u>Transformations:</u></p> <p>Definition and realization of the means or the tooling.</p> <p>The design and realization process of tooling follows the steps described below:</p> <ul style="list-style-type: none"> • specifications; • design; • realization; • adjustment; • validation. 		
<p><u>Output:</u></p> <ul style="list-style-type: none"> • means or tooling; • maintenance plan (allocations, etc.); • monitoring plan/periodical inspections; • instructions for the use of the means or the tooling; • computer programmes of the machines; • consumables associated with the means or tooling; • protective equipment; • compliance/validation report; • DDF of the specific means or tooling and the associated user file. 		
<p><u>Formalization:</u></p> <ul style="list-style-type: none"> • physical object or software and the documented information. 		
<p><u>Best practices:</u></p> <p>The rules that apply to the elaboration of the DDF (see RG.Aero 000 14) are directly applicable to the DDF of the tooling.</p> <p>FMECA of the means and the tooling.</p> <p>The means and tooling to be used in the product production process are included in the list of means and tooling of the M-BOM and are referred to in the manufacturing routine or in the operating instructions in the phase where they shall be used.</p>		

7.2.9 Documented manufacturing and inspection information records (DMIIR)

The DMIIR is a part of the operation. The elements to be taken into account are identified in Table 9 below:

Table 9 — Documented manufacturing and inspection information records

<p>Aim: The documented manufacturing and inspection information records (DMIIR) are used to:</p> <ul style="list-style-type: none">• make records of the evidence of the product compliance, whether recurrent or occasional;• establish the traceability of the operations or implemented products used or imposed in the “in use” phase. <p>These elements are independent of all the information pertaining to the validation of the industrialization, which is part of the MIJF, but may contribute to it.</p>	<p>Owners:</p> <p>Designer Industrial project manager Quality Procurement manager Methods</p>	<p>Users:</p> <p>Quality inspector Quality assurance Procurement manager Production manager Customer</p>
<p>Input and opportunities:</p> <p><u>Technical data:</u></p> <ul style="list-style-type: none">• MIFC = organization of the checkpoints;• manufacturing and inspection routine;• DDF = list of the parameters that guarantee the performance of the product;• performance of the means (impacts the depth of the measurements);• quality system of the production entity = the method to control process parameters, skills, etc.;	<ul style="list-style-type: none">• test plan if exists = list of the functional parameters to be checked;• industrial validation (IV) operations = list of the specific or programmes’ lessons learned to be implemented in terms of inspections (means);• regulatory and normative environment = rules and requirements pertaining to the technologies or traceability, for example;• contractual requirements.	
<p>Transformations:</p> <p>The DMIIR of proof of compliance are usually imposed by:</p> <ul style="list-style-type: none">• the contractual requirements;• the definition (test plans, definition key characteristics);• the operating instruction of the subsequent operations;• the standards and regulations associated with the technologies implemented;• the compliance of the marking/labelling and the associated identifications; <p>Their relevance lies in the level of risk incurred if they are not implemented.</p> <p>They are consistent with the tooling, instructions, skills, etc.</p> <p>They may be sourced from suppliers.</p> <p>The traceability DMIIR can be required by:</p> <ul style="list-style-type: none">• the regulations;• the quality rules (which may be responses to the regulations). <p>They are mostly records of dates, batch references, configuration management information (deviations from the configuration or changes to the configuration - see EN 9223-100), operator names, etc.</p> <p>The notion of deviation allows non-conformances forecast in the MIF to be pre-accepted, pending the update of the DDF.</p> <p>All the DMIIRs are implemented by the production method teams (industrialization or inspection).</p>		
<p>Output and interfaces:</p> <p><u>For every recurrent manufacturing run:</u> recording medium of the data compatible (internal or requirements imposed on suppliers, for example) with the industrial environment from which the data are extracted.</p> <p><u>For delivery, packaging and transport controls:</u> specific report to be defined.</p> <p><u>For the acceptance tests:</u> specific report to be defined.</p> <p>Certain information can be exported to the customer (according to the contractual clauses).</p>		
<p>Formalization:</p> <ul style="list-style-type: none">• logbook of the parameters (e.g. inspection cards);• unit or batch acceptance report for an operation or for the finished product;• complete individual inspection register (IIR) kept internally and partial IIR exported and adapted to meet the customer’s needs;• test report;• statement of conformity and/or completed EASA Form 1;	<ul style="list-style-type: none">• completed workshop log sheet (based on the content of the WO);• product logbook;• versions of the MIF or the MIJF;• CE certificate;• “green passport” (records of the constituent parts, substances or other in the REACH list);• calibration form.	

Best practices:

The MIFC clearly defines the specific checkpoints (and places) in order to minimize the risks of impacts (cost, time, quality) = compromise to be reached.

The standard of the production entity's quality system defines the "process" inspections.

The implementation of the SPC on the means of production guarantees the compliance of the products and improves knowledge of the industrial means of production.

Industrial validation guarantees the completeness of the DMIIRs.

The record is made as early as possible and avoid successive re-entry of the data by opting for a unique storage database.

The method used to determine the information is described in the associated instruction.

Certain data are kept for the entire lifetime of the product or the programme, depending on the applicable requirements.

The DMIIRs of the first production runs are used for the IV (MIJF).

In case of external distribution of the DMIIRs, the terms are to be provided for in the contract.

7.2.10 Skills

A skill is a part of the operation. The elements to be taken into account are identified in Table 10 below:

Table 10 — Skills

<p>Aim: To obtain the information required to:</p> <ul style="list-style-type: none"> have a human resource perform the activities associated with: <ul style="list-style-type: none"> industrialization; manufacturing, assembly or logistical operations; checks (verification, validation) of the activities related to industrialization, production and logistics; be capable of proving (internal and external authorities) the suitability of the resources to the activities to be performed. 	<p>Owners:</p> <p>Industrialization manager Production manager</p>	<p>Users:</p> <p>Industrialization Production Logistics Subcontracting management Quality HR</p>
<p>Input and opportunities:</p> <ul style="list-style-type: none"> request raised by industrialization; request raised by production; company HR policy; requirement formulated by an external authority (the customer, an administrative, regulatory and normative authority, etc.). 		
<p>Transformations:</p> <p><u>Prerequisites:</u> The role of the manager consists in defining the technical skills specific to the process (complementing the global HR policy).</p> <p><u>Phase 1:</u> For each process used to make the expected product, characterize the required skills:</p> <ul style="list-style-type: none"> collect the needs and, if necessary, reformulate them with the requesting parties in order to meet them as closely as possible; identify the regulatory and contractual constraints (if necessary) associated with the request; produce the job description (roles, responsibilities, technical skills, behavioural skills, specific qualifications, necessary certifications, activities, etc.) and send it to HR (for internal transfers, acquisition of the skills through training or recruitment). 		<p><u>Phase 2:</u> Find or train the competent resource (HR process).</p> <p><u>Phase 3:</u> Integrate and validate the required skills of the human resource:</p> <ul style="list-style-type: none"> check the adequacy between skills, qualification/position and necessary authorization if necessary; if necessary, certify the resource for the job; have the necessary justifying documents for the position in the HR tools and accessible to the resource (on their workstation via instruction sheet for example) with the renewal dates. <p><u>Phase 4:</u> Maintain the skills (HR process) by maintaining the authorizations and certifications and through practice.</p>
<p>Output:</p> <ul style="list-style-type: none"> available human resource with the skills and certifications matching the jobs to be filled; job descriptions for the identified specific skills. 		<p>Interfaces:</p> <ul style="list-style-type: none"> human resources; quality.
<p>Formalization:</p> <p>(electronic or not)</p> <ul style="list-style-type: none"> job description; interview form; list of the constraints of the job; training plan/change management. 		
<p>Best practices:</p> <p>Include HR in the process right from the identification of the need (at the time of the investment, in the bid process).</p> <p>Monitor performance/critical points twice a year.</p> <p>Establish transparent relations between HR/the resource/management.</p> <p>Anticipate departures and the risk of losing skills.</p>		

7.2.11 Workstation

The workstation is a part of the operation. The elements to be taken into account are identified in Table 11 below:

Table 11 — Workstation

<p><u>Aim:</u> The workstation is the smallest internal or external manufacturing and/or inspection unit that the manufacturer has decided to manage from the perspective of:</p> <ul style="list-style-type: none">• calculation of workloads;• order priority. <p>The workstation is based on an optimized division of the manufacturing of given products. It may use manufacturing and inspection processes. The processes are linked without a queue. It includes one (or more) stations, which are geographically defined areas, and performs a logistical function: point of departure and arrival for the movements of items, document, tooling, etc., to the workstation.</p> <p><u>Examples:</u> machining, assembly, 3D inspection or loading workstation, test benches, laboratories, etc.</p>	<p><u>Owners:</u> Managers of manufacturing and inspection in a “use” context Manager of industrialization (including methods) in the “design” context</p>	<p><u>Users:</u> Industrialization Production</p>
<p><u>Input:</u></p> <ul style="list-style-type: none">• validated workstation;• work order (WO);• instruction sheets;• constituents, raw materials, etc.;• tooling;• skills, HR.		
<p><u>Transformations:</u> Perform transformation and/or inspection operations that create added-value to the product.</p>		
<p><u>Output:</u></p> <ul style="list-style-type: none">• added-value of the item;• operating times, production costs;• traceability of the operations and records pertaining to quality;• real-time analysis of production bottlenecks.	<p><u>Interfaces:</u></p> <ul style="list-style-type: none">• stores/stations/procurement;• routines;• means;• processes;• industrialization;• quality;• logistics;• maintenance.	
<p><u>Formalization:</u></p> <ul style="list-style-type: none">• workstation settings in the production tool management system;• physical availability of the workstation (workload).		
<p><u>Best practices:</u> Workstation description containing the safety instructions of the workstation. The workstation is to be installed at the earliest possible stage of the design phase, so that the prototypes are manufactured on these workstations, allowing their validation. Involvement of all the actors and the interfaces in the validation of the workstation.</p>		

8 Elaboration process and content of the justifications associated with the MIF

8.1 Objective

On the basis of the manufacturing and inspection justification plan (MIJP), the MIJF is intended to demonstrate the qualification of the production system. The qualification of the production system essentially allows serial production to start under controlled conditions, in order to reduce any contingencies and technical events. The MIJF may also meet a need for regulatory certification.

Additional work is done on the first serial-produced samples to demonstrate reproducibility and finalize the MIJF.

The MIJF provides coherent and structured information that can help to make decisions on manufacturing and inspection change instruction or to resolve anomalies during the product's lifetime. It contributes to the processing of risks and impact analyses when product optimization/simplification actions are taken, and facilitates the planning of obsolescence management.

It is made up of a number of specific (to the product) or generic (process, production tool, etc.) documented justifications that meet the requirements for the part concerned.

8.2 Establishment and content of the MIJP

8.2.1 Establishment of the MIJP

The industrial project manager is responsible for elaborating the MIJP.

The MIJP is established right from the start of the industrialization process and is gradually consolidated on the basis of a schedule (milestones, reviews, expected justifications, tests to be performed, availability of the necessary means, realizations and testing of the prototypes, etc.) that is realized. This schedule is consistent with the industrialization and production plans. The MIJP may be included in the industrialization plan.

The schedule for the collection of the justifications is established from the higher level of the product breakdown structure towards the lower levels.

NOTE The justification of a requirement can be acquired further to successive works on several levels of the product breakdown structure.

Input data and scope to be taken into account are the same as those used to produce the MIF concerned.

EXAMPLE The industrialization plan.

Nevertheless, an additional analysis allows to verify that these input data are complete, e.g. the technical speciality aspects, lessons learned, industrial infrastructures/interfaces, breakdown of the justification requirements to a supplier, search for influential parameters, improvement of the processes readiness level, etc.

The elaboration of the MIJP takes account of the existing assets of the production entity, such as its organization, the available skills, its good practices, the state of the art, the existing processes, preceding justifications, etc.

The MIJP is validated according to the organization's internal processes or by a third party, if a requirement so demands (regulations, customer, etc.).

8.2.2 Content of the MIJP

The MIJP contains:

- the list of all the applicable requirements (including those pertaining to regulatory certification) and the corresponding acceptance criteria (margins, etc.);
- the breakdown of each requirement, expressed in terms that can be used directly to specify the justification(s) to be acquired. This breakdown may be irrelevant if the requirement is sufficiently explicit or elementary in itself;
- for each of the justifications to be acquired:
 - o the nature of the works intended to acquire the justification information [inspection, analysis, demonstration and test (IADT)] - see Annex C for examples;
 - o the characterization of the resources (skills, test benches, etc.) to be implemented to perform these works, with details of whether each resource is, for example, available, imposed or to be acquired;
 - o the “target date” for the acquisition of the justifications, in keeping with the industrialization plan and the production plan;
 - o the person responsible for the justification.

In addition to the applicable requirements, all the documents in the MIF (see 7.2) are to be justified. Generic items are justified on the basis of the existing means of control of the organization's quality system, while ensuring that they are well adapted to the part to be produced and are maintainable.

Figure 7 shows the main sources of work and the justifications synchronized with the product development:

- the MIF elaborated in an iterative manner (up to obtain the validated MIF, see Clause 10) according to the development milestones. The acquired justifications are validated in successive reviews and provide input for the MIJF;
- engineering studies (process FMECA, margin analysis, modelling, design dimensions, etc.) that, in particular, allow to reduce the risks of variability of the influential parameters;
- the data used to validate the means and tooling allow to ensure that the corresponding requirements will be met (manufacturability, etc.);
- the adjustment of the manufacturing and inspection processes (in particular the special processes) by using qualification or industrialization prototypes, test samples, etc., and allowing to provide proof of feasibility and compliance;
- other works and proof, such as the technologies, standards, internal rules (operator qualification/certification, etc.), customer requirements, designer tests/calculations, lessons learned, etc.

All this information is used to conduct the FACI, which allows the production system to be qualified and the MIF and the MIJF to be validated.

In practice, the initial FACI is an essential step required to authorize the delivery of the first products to the acquirer and to validate the production system that is representative of serial production.

In order to reach the FACI, it is necessary that reproducibility works are completed, such as:

- capability measurements on the key characteristics;
- whenever necessary, measurement systems analyses (MSA);
- capability by analogy.

Additional works may be performed in parallel, such as:

- ramp-up;
- automation of the means;
- multiplication of the means;
- lessons learned on a statistically more representative quantity of units;
- findings of actions for improvement designed to produce margins.

All these works contribute to the pronouncement of a “full industrial serial production capacity” FACI and to the maintenance of the proof acquired in the initial FACI.

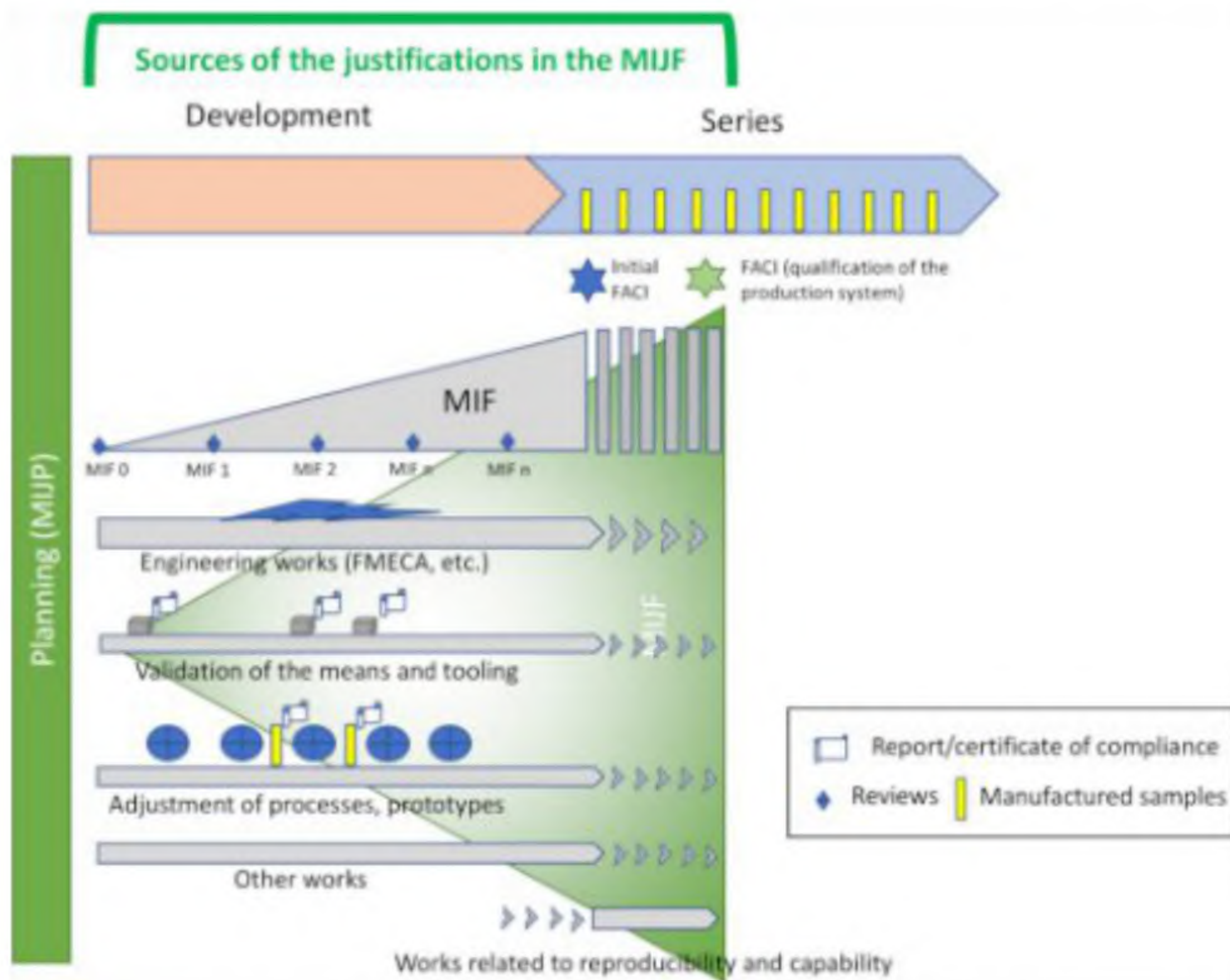


Figure 7 — Example of sources of justification in the MIJF

NOTE EN 9145 can be used to help to define the justification items (see Annex C).

An example of the presentation of a MIJP can be found in Annex A.

8.3 Establishment and content of the MIJF

8.3.1 Establishment of the MIJF

The MIJF is gradually compiled at the same time as the MIF and as the corresponding validation works are performed.

The MIJF is consolidated with the proof obtained from the lower levels of the product breakdown structure towards the higher levels.

The MIJF is validated according to the organization's internal processes or by a third party, if a requirement so requires (regulations, the customer, etc.). The MIJF is an internal file of the manufacturer. Depending on the contractual requirements, this file may be presented, audited or sent to the customer or the authority.

The establishment of the MIJF can be broken down into three successive tasks:

- the compilation of the justifications identified in the MIJP (see 8.3.2);
- the realization of a summary report of all the justification works;
- the validation of the justifications in a review (see Clause 9).

An example of presentation of an MIJF is enclosed in Annex B. A specific formalization of certain items in the MIJF may be contractually required by the customer or the authority.

These items may be included in an industrialization justification file.

8.3.2 Content of the MIJF

The MIJF can be presented in three parts:

- a first “reference” part, which contains the references of the related documents and products, or any other references that can be used to characterize the scope concerned of the validation sheet;
- a second part in the form of a summary table containing:
 - o the description of the works, as identified in the MIJP;
 - o the expected kinds of justifications;
 - o the works to be realized to obtain the expected proof of justification;
 - o the references of the documents containing the proof of justification;
 - o the person responsible for the validation of the results of the justification works and the proof;
 - o the compliance status;
 - o if necessary, any observations, such as specified requirements that are not met, difficulties encountered, the state of progress of the justifications, their analysis and the corresponding risks, the position of the result achieved relative to the tolerance, etc.;
- a third part in the form of a balance sheet summarizing:
 - o the information pertaining to the review (purpose, date, preceding review, etc.);
 - o the list of required and present participants;
 - o the impact review of the MIF with comments or additional works required, if necessary;
 - o the confirmation of the availability of the proof for the lower levels;
 - o the conclusion of the review (validation approved, partial validation or validation refused);

- o the action plan and its owner;
- o proposals for improvement, in particular with regard to the residual risks.

NOTE An example of the formalization of the MIJF is enclosed in Annex B and a list of examples of kinds of proof is available in Annex C.

The MIJF should contain the necessary information to ensure the traceability and the history of the works and the corresponding results, including works that had to be repeated several times due to technical events or adjustment failures. The aim of this information is to provide lessons learned.

8.4 Qualification and certification of the processes

The purpose of the qualification and/or certification of the processes is to obtain the validation by an interested party of the compliance of certain elements (in particular the special processes) implemented by industrialization.

When these processes are subject to a qualification, the interested parties may be internal (quality, inspections, etc.), the customer or an organization mandated by the customer. Qualification is based on the internal requirements of the organization and/or the contractual requirements.

When these processes are subject to the regulations, the interested parties may be the authority or an organization mandated by the authority. Certification is based on the requirements demanded by an authority.

Certification is a process in which the certifying authority issues a certificate or a document authorizing an industrial manufacturer or integrator to produce.

The items demanded by the certifying authority are justified on the basis of the proof obtained for the MIJF. However, the formalization may be different.

9 Validation of the MIF and the MIJF

The validation of the MIF and the MIJF is a formal process that ensures that the manufacturing and inspection process allows to obtain a product compliant with its definition (according to the objectives set in terms of quality, cost and cycles/rates) in a reproducible manner and, therefore, qualifies the production system.

The MIJF is finalized in a review conducted by the competencies and authorities defined by the production organization in order to take a decision on the global status of the justification of the MIF. This review also verifies any potential changes to the MIF since the work started on the MIJF to make sure that they are compatible.

The first step of the validation consists in validating the MIF on the basis of the MIJF in order to demonstrate the producibility of the definition. Reproducibility is demonstrated by producing a given quantity of samples that is defined in advance according to the kind of product, the technology, the standards, the applicable contractual requirements, etc.

On a given level of the product breakdown structure, the MIF is validated:

- by validating each constituent part of this MIF according to the organization's practices and quality system;
- by validating the MIJF of this same level.

The global validation of the MIF and the MIJF of the end product is based on the compilation and the validation of all the MIFs/MIJFs of the lower levels (bottom up).

This validation may be:

- complete and allow the MIF to be used;
- partial and require the list of items still to be validated in a subsequent review. E.g. a partial validation can authorize a pre-serial production run or procurements with long lead times, under the permissible conditions;
- refused and require an action plan.

The results of the validation are recorded and the justifications are kept and analysed in the FACI.

NOTE A review report form is available in part 3 of Annex B.

10 Use of the MIF

The MIF can have several reference statuses, depending on the reference status of the part (prototype, pre-series, serial, etc.). Changes between these reference statuses are managed according to the provisions of Clause 11.

NOTE A reference status is a status that has at least been validated internally in accordance with the provisions of the production entity.

The validated MIF constitutes the reference file for all customer orders.

WOs and purchase orders are raised to launch the manufacturing of the parts concerned on the basis of a reference status of the MIF.

The WO contains the execution instructions (for the production run concerned) and all the instructions and forms used by the production actors allowing to realize and record the tasks defined in the MIF and the data associated with the operations.

Anomalies or non-conformances may be observed on the part (see EN 9223-100) during the manufacturing process. The root cause analysis and rework and repair activities may result in changes to the MIF and/or the MIJF (see Clause 11). The rework and repairs are recorded in the WO and/or the waiver.

NOTE If a repair or a rework routine and the corresponding instructions are created, they can be included in an update of the MIF of the product concerned. Any justifications of these routines are included in the corresponding MIJF.

11 Change of the MIF and the associated justifications

The processing of changes of the MIF, the MIJP and the MIJF allow to guarantee that the production system remains operational.

Changes may be made to a given reference status of the MIF and/or the MIJP and/or the MIJF further to:

- obsolescence (all resources);
- changes to the product definition;

- changes to the industrial scheme (internal or external);
- changes to the production process (events, human factors, etc.) that may degrade the production system and invalidate the initial MIF;
- improvements/corrections to the process (correcting malfunctions or non-conformities, or opportunities for improvement, taking into account of the lessons learned, etc.), e.g. in the event of repairs or rework during production;
- regulatory or contractual changes;
- changes to a subcontractor's MIF;
- changes to the contractual maintenance activities;
- the interruption of production for longer than a pre-defined period and in keeping with the need to re-qualify the production tool and to obtain new certifications, where appropriate.

Change control of the MIF entails:

- assessing the impacts of the change to be made (costs, impact on the production in progress, impact on other programmes, impact on the industrial scheme, impact on the product definition, impact on the justifications of the MIF, etc.);
- planning the implementation, in view of the resources and the cost and time objectives of the programme, and of the performance objectives of the production tool;
- updating and availability of the constituent parts of the MIF and, if necessary, of its justifications;
- validating the MIF and the MIJF, in accordance with the provisions of Clause 9.

When the changes to the MIF impact the DDF (changes of imposed processes, changes affecting at least one of the physical and functional characteristics of the product, etc.), the updated MIF can only be validated once the DDF and the definition justification dossier (DJD) of the product have been updated and validated.

It is essential to make sure that the changes to the MIF do not result in any regression in meeting the requirements and the performances already achieved. The result of the non-regression analysis is recorded in the documentation management system.

Changes to the constitutive elements of the MIF and its associated justifications are processed according to the organization's document management and configuration management rules.

The industrial's reference framework defines the change management process according to the applicable configuration management requirements of the organization or the contract. In particular, it specifies the entities concerned and the competent authorities (internal or external, see Figure 2) involved in the decision-making process.

NOTE Best practices produce a definition of the classification rules for changes (e.g. major/minor, or classes 1 to 3), according to the criteria defined in advance by the organization and the requirements of the customer and the authorities. This classification categorizes the level of the validator (see EN 9223-100).

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The MIF is to be maintained throughout the duration of the production of the part concerned. Following an interruption in production, and in the absence of any particular applicable requirement, the MIF should be updated, or at least consider the need to update.

NOTE EN 9102 requires a new FACI when production is interrupted for more than 2 years.

Annex A (informative)

Example of the presentation of a manufacturing and inspection justification plan (MIJP)

References of the input data:

MIF reference:

Table A.1 — Example table within MIJP

IDENTIFIED REQUIREMENTS	BREAKDOWN OF THE REQUIREMENT	DESCRIPTION OF THE WORKS ^a	NECESSARY RESOURCES			"OBJECTIVE" DATE	OWNER	OBSERVATIONS ^b
			LIST	AVAILABLE	TO PROVIDE + MEANS OF ACQUISITION			

NOTE It is possible to add one or more columns in order to adjust the available information (e.g. the applicability of the works according to the units to be produced).

^a Specify the kinds of justification works, e.g. FMECA, dimensional check, reliability calculation, realization of a prototype (see Figure 7).

^b When they exist, refer here to the specific test plan/programmes (technical feasibility, capability, etc.). When prototypes are identified, it is possible to mention the designation of those that will be dedicated to the tests contributing to the justification and to specify the deviations from the planned serial production tool.

Annex B (informative)

Example of the presentation of a manufacturing and inspection justification file – MIJF

The MIJF is presented in three parts:

- a first “reference” part containing the references of the documents and associated products;
- a second part in the form of a table summarizing the works, the acquisition of proof and the compliance status (see Table B.1);
- a third part in the form of a review report (see Table B.2).

When the changes to the MIF impact the DDF (changes to the imposed processes, changes affecting at least one of the physical and functional characteristics of the product, etc.), the updated MIF can only be validated once the DDF and the definition justification dossier (DJD) of the product have been updated and validated.

1st part: References

- a) Position in the product breakdown structure:
- b) DDF reference:
- c) MIF reference:
- d) MIJP reference:

Table B.1 — 2nd part: Summary table (with examples)

DESCRIPTION OF THE WORKS (as identified in the MIJP)	KINDS/DETAILS OF THE JUSTIFICATION (WHAT) ^a	NATURE OF THE WORKS PRODUCING THE PROOF (HOW)	REFERENCES OF THE DOCUMENTS CONTAINING THE JUSTIFICATION ^b	PERSON RESPONSIBLE FOR VALIDATING THE RESULT	COMPLIANCE STATUS ^c	OBSERVATIONS ^d
<i>e.g. CPk, etc.</i>	<i>SO</i>	<i>Calculation as per rule xxx</i>	<i>CPk report ref. xxx</i>		<i>Compliant, but with no margins</i>	
<i>Validation of the specific tooling</i>	1 Complete list of the tooling 2 Validation of the DDF of the tooling 3 Operational validation of the tooling 4 Integration of the tooling in the metrology database	1 Extraction of the MIF and field review 2 Design review of the tooling 3 Production of a prototype and compliance review, including lessons learned from the workshop 4 Extraction from the metrology list	Meeting report ref. xxx Review report ref. xxx Review report ref. xxx Prototype no. yy Metrology note ref. xxx		<i>Compliant, but to be completed with additional units</i>	
<i>Completeness and validation of the instructions in the MIF</i>	1 List of the instructions in the MIF 2 Validation of the documents 3 Validation in use	1 Extraction of the MIF and field review 2 Examination by quality 3 Report on the lessons learned on the prototypes				
<i>Process validation</i>	1 Certificate of the authority 2 FMECA	1 Elaboration of the process file 2 FMECA according to the reference document XXXX				

^a See Annex C for examples of kinds of proof.

^b Identify the documents given to the customer or the authority.

^c Decide on the compliance: suggested ranking:

- compliant: the evidence demonstrates complete compliance with the expected result;
- partially compliant/non-compliant: all the planned works were completed, but the results are not all satisfactory. Actions are expected to achieve compliance;
- pending: the demonstration of compliance with the specification is planned, but has not yet been performed.

^d Actions expected to achieve compliance shall be recorded in this column.

Table B.2 — 3rd part: Review of all the justifications

Review report:		
Reference of the MIJF:	The review took place on:	Reference of the preceding review (if not the initial review):
Compulsory participants:		Absent participants:
Impact review of the reference MIF ^a /MIF in progress: <div> <input type="checkbox"/> comments <input type="checkbox"/> additional works required </div>		
Confirmation of the availability of the MIJFs of the lower levels; <div> <input type="checkbox"/> yes <input type="checkbox"/> no </div>		
Important or significant comments on the analysis of the available results (strengths/weaknesses; context; mention the rework):		
Conclusion: <div> <input type="checkbox"/> MIJF validated on the basis of the reference MIF <input type="checkbox"/> MIJF validated on the basis of the current MIF <input type="checkbox"/> Partial validation of the MIJF (with identification of the justifications still to be acquired) <input type="checkbox"/> Validation of the MIJF refused (with action plan) </div>		
Level of MRL achieved:		
Action plan:		Owner: Deadline:
Proposals/paths of improvement:		
Date:	Owner's signature:	
^a The reference MIF is the MIF used to produce the current MIJP.		

Annex C (informative)

Examples of justification works to be performed

The content of the MIJF is described in Table C.1, column no. Three – *Kinds of works to be performed*.

It is first necessary to check that all the documents in the MIF (1st column):

- are up to date in the information system and available for use;
- have been validated by the appropriate authorities;
- have produced lessons learned on their use.

The FACI is also used to validate all the content of the MIF and, consequently, of the MIJF.

Table C.1 — Example content of MIF

Content of the MIF	Examples of expected proof (WHAT)	Kinds of works to be performed (HOW)
MIFC	Document up to date and validated	Review of consistency with the design Initial FACI completed Cycle indicators (on-time delivery) Governance/procurement strategy risk analysis
Manufacturing bill of materials	All the means are available and suitable	Cycle indicators (on-time delivery) Production of a prototype and lessons learned Initial FACI completed (for each level of the product breakdown structure) Governance/procurement strategy risk analysis
Manufacturing and control inspection routine	Producible and compliant routine that achieves the expected performance results (costs, time, quality)	Cycle indicators (on-time delivery) Realization of a prototype and lessons learned Initial FACI completed (for each level of the product breakdown structure)
External procurement file	Performance of the procurement strategy	Governance/procurement strategy risk analysis FACI of the supplier(s) Supplier performance indicators (costs, time, quality)
Operations	Suitability of the procedure	Realization of a prototype and lessons learned from the operators Initial FACI completed (for each level of the product breakdown structure) and FACI Procedure FMECA
Processes	Achievement of a producible and reproducible process	Process FMECA to define the key characteristics of the process Laboratory validation report Test reports, test pieces, quality audits Operator lessons learned and achievements Validation by third parties (authority, customer audit, etc.) Designer test reports Capability results of the product and process characteristics FACI

Content of the MIF	Examples of expected proof (WHAT)	Kinds of works to be performed (HOW)
Instructions	Validation of the working instructions	Process FMECA Co-reading with the operator and quality Lessons learned on the prototypes FACI
Associated tooling, means and computer programmes	Validated and operational tooling and means are available	Tooling/means/software verification report Validated definition data file of the tooling/means/software List of available tools present in the information system Proof of metrological monitoring Measurement systems analysis (MSA) Periodical inspection report FACI
DMIIR	Availability and traceability of the information	Review of all the records and the corresponding reinforced inspections Report of the verification of the marking and associated identification
Skills	Need for skills expressed and available	Up-to-date proof of the certification and authorization of the personnel concerned Skills matrix
Workstation	Workstation complete and compatible with the realization of the product Compliance file with the legal and regulatory requirements (environment, labour code, etc.)	Machine file/validation of suitability for commissioning Regulatory and/or periodical inspection report

Annex D
(informative)

Example of the transformation of the definition bill of materials into a manufacturing bill of materials according to the industrial organization

Figure D.1 shows the different mapping possibilities between the definition breakdown structure and the production breakdown structure of a configuration item.

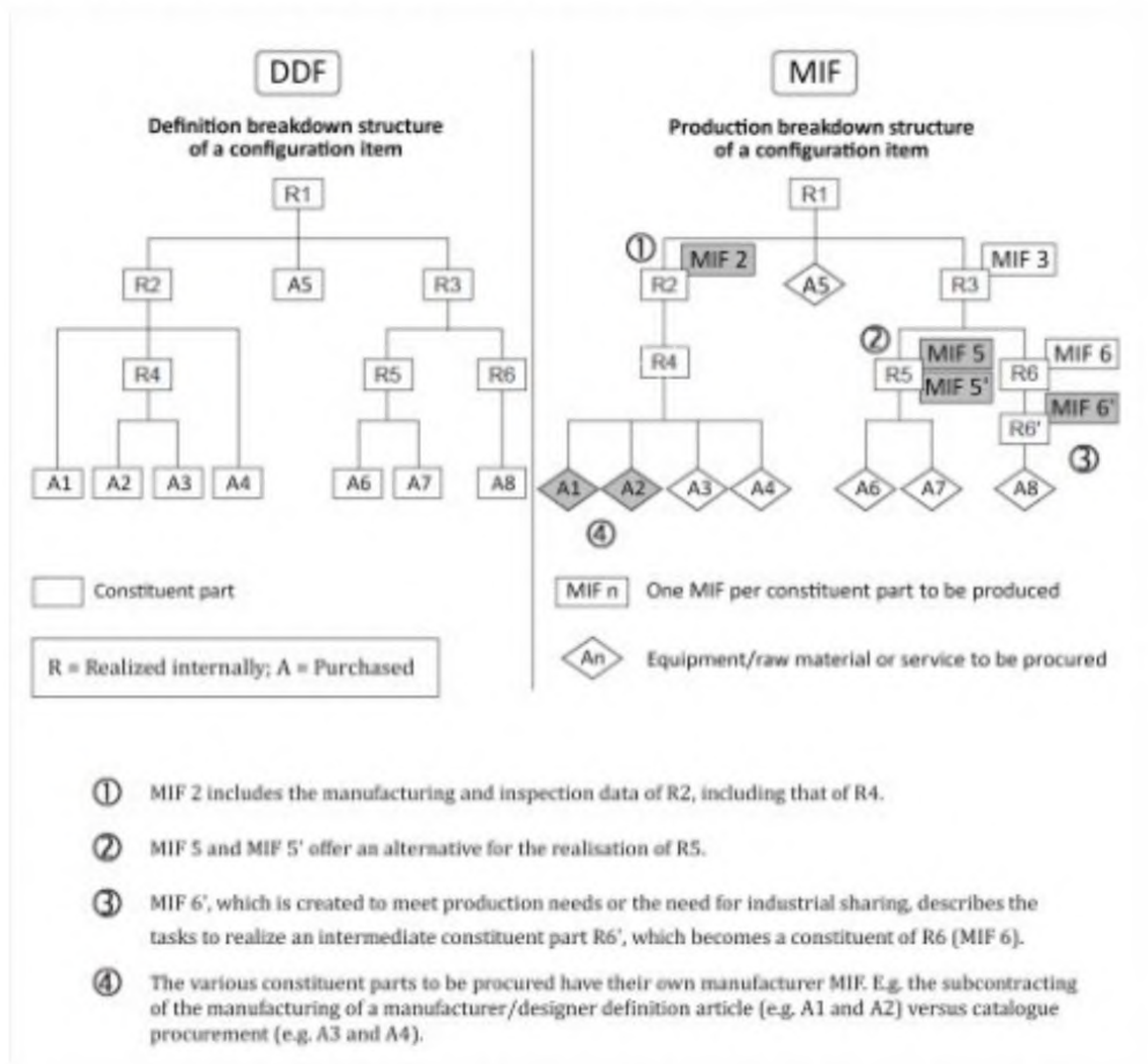


Figure D.1 — Example of the transformation of the definition bill of materials into a manufacturing bill of materials according to the industrial organization

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