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Comments to ISO/DIS 22163 issued 15 Febr. 2022

A public document

Color code:

Blue: comments or explanations

Red: suggested corrections or proposed improvements

process or method that has been shown to work well, succeeds in achieving its objective(s), is widely accepted and therefore can be recommended as an approach

Comment: widely acceptance is maybe not the right criteria. I suggest:
process or method that has been shown to work well, succeeds in achieving its objective(s), is accepted by the process owner and therefore can be recommended as an approach

3.1.2.13 production

activities to realize products including overhaul and repair

Note 1 to entry: Part of an organization's value chain.

I suggest conforming to chapter 8.5.1.1.1 General - Note:
activities to realize products including installation, commissioning, overhaul, repair and modernization/refurbishment.

3.1.2.20 quality assurance method

method applied to qualify, verify or validate the implementation of requirements in order to focus on error prevention rather than detection

EXAMPLE 1 In design and development.

EXAMPLE 2 FMEA, FMECA, quality function deployment.

Comment: splitting into Example 1 and 2 is wrong
Example: QA methods in in design and development processes are e.g., FMEA, FMECA, QFD, Design Reviews, FEA ...

3.1.2.21 Quality deficiency cost

Two improvements suggested

Suggestion 1.

Note1-to entry -: Quality deficiency cost can be distinguished by causes (e.g. **failure in tender-, design & development-**, production-, purchasing-, or project management **processes**) and by phase of occurrence (e.g. tender, design, production, post-delivery).

Why? Suggestion to focus on improvement by process owners, to avoid finger pointing and not blaming individuals.

Suggestion 2.

Note1-to entry -: Quality deficiency cost can be distinguished by causer, e.g. sales, engineering, production, purchasing, or project management. ~~and by phase of occurrence (e.g. tender, design, production, post-delivery).~~

Why? Although one could distinguish QDC between by phases, it would be misleading a reader. While identifying the causes of QDC will lead to clearly addresses actions to reduce QDC (e.g. addresses to Process owners of sales processes, or engineering processes etc.) with a certain confidence that actions will be taken. The other approach to identify QDC be phases, will lead to nothing. Example: we know that the very high QDC will be captured in the warranty phase, but these were caused e.g., already in the bid phase. Hence, reporting a high number in the warranty phase will not necessarily trigger actions to improve the tender management process. Therefore, it would be better to capture all QDC (whenever they occur) and assign them to Process owners which shall take care for their business improvement.



3.1.3.2 functional maturity (*Please pay this comment utmost attention since it impacts many clauses such as 8.1.3.9 + 8.1.4.2 + 8.3.2.1 + 8.3.4.1 + 8.4.1.1.2 + 8.4.1.1.5., and maybe more that I have overlooked*)

Currently, the consideration of maturity of non-functional requirements (performance and other non-functional requirements, except integration requirements) is not included. Therefore, functional maturity (3.1.3.2) should still be called “**operational maturity**” (Einsatzreifegrad) as in ISO/TS 22163 (encompassing functional and non-functional performance requirements, except integration requirements). Integration maturity remains unchanged (Integrationsreifegrad) as a separate term.

Explanation:

The purpose of the maturity definition is to apply risk-based thinking in the requirements management process. It is used to plan the necessary extent and level of controls, means functional and performance tests, to validate the (customer) specification in dependence from the maturity level (high maturity – less risk, hence less QA-methods/validation tests to apply) (low maturity – higher risk, hence more or all planned QA-methods/validation tests fully to apply).

Case:

A proven traction motor was developed for European climatic conditions and manifold sold to European Operators. Now the same motor shall be used for a train operating in Asia under tropical climatic conditions (non-functional requirement -> performance requirements are massive changing). The motor was never tested for tropical climate. However, the functional requirements are 100% identical. So, the functional maturity is very high, hence no additional validation tests would be necessary? No, this conclusion would be wrong because of the non-functional performance requirements. The tropical climatic conditions would be ignored, but it would be necessary to test the motor under tropical conditions to minimize the risks.

Suggestion:

3.1.3.2 functional maturity: degree of fulfilment of functional and non-functional requirements (performance + other non-functional requirements, except integration requirements) of a product or service.

EXAMPLE 1 Not existing, under development, ready to use, in use.

EXAMPLE 2 Not fulfilling, partially fulfilling, fully fulfilling.

3.1.3.3 functional requirement

requirement that specifies a function that a product or a service shall perform

EXAMPLE: Maximum passenger capacity for a train car, possibility to add a car in a metro vehicle.

Comment: the maximum passenger capacity could be seen more as a performance requirement than a functional requirement. I suggest changing into form, fit or function approach such as: **dimensions of a train car, possibility to add a car in a metro vehicle**



3.1.3.5 integration requirement

requirement of a product or service to describe how a constitutive system/subsystem/component interfaces with others, to perform an integrated function

EXAMPLE Weight, external dimension, kinematic envelope, power supply requirements, network (communication).

I suggest: requirement of a product or service to describe how a constitutive system/subsystem/component interfaces with others, to perform an integration function

3.1.4.3 deliverable

type of output for the scope of supply to fulfil set requirements

EXAMPLE User manual, maintenance manual, test reports, test equipment, training, spare and support parts.

I suggest: type of output for the scope of supply to fulfil a set of requirements

In addition, I wished that the Working Group would including in chapter 3.1 the terms

Project life cycle or project life-time (because it is mentioned in 3.1.2.15 Note 5, and 9.1.3.1, but not explained)

Repair (mentioned many times)

Corrective maintenance (suggested to be included in 8.5.5.1)

Preventive maintenance (mentioned in 3.1.2.12, 3.1.3.10 Note 4, and 8.5.1.4)

Predictive maintenance (mentioned in 8.5.1.4 ii.)

Modernization

Refurbishment

Chapter 4

4.4.3 f) comment: in this context risk-based thinking (0.3.3) applies much more than risk management. Hence, the suggested FMEA is not adequate, but any other classification scheme applying risk based thinking-to identify, e.g. external key provider, key customer, A-,B-, C-class material, or A-, B-, or C-class projects.

Suggestion:

f) define criteria, utilizing risk based thinking (e.g. ~~FMEA~~ for identification of external key provider) to determine the type and extent of controls in its processes.

Chapter 5

Suggestion just for clarification and better understanding:

5.3.1.c) document and communicate updates of responsibilities and authorities for relevant roles (e.g. ~~process~~ ownership);

Chapter 6

No comments

Chapter 7

7.1.5.3 Monitoring and measuring resources — Supplemental

The requirements specified in 7.1.5.1 and 7.1.5.2 shall apply to:

- a) all monitoring and measuring resources used for verifying the conformity of products and services to their requirements;
- b) all tools ensuring valid and reliable results, especially when used in special processes (e.g. torque wrench and crimper).

The organization shall establish, implement and maintain a process for calibration or verification, or both, of monitoring and measuring resources as well as of tools referenced in 7.1.5.3 b). This process shall include:

7.2.1 Competence — Supplemental

Comment: Soft skills are no professional term to be used in a standard. Universities use the terms technical, social, and individual skills

NOTE 1 Competence can include **technical skills such as** product, process or project knowledge, software tools, techniques (e.g. quality assurance methods) and ~~soft~~ **social** (e.g. teamwork, communication, etc.) as well as **individual** (e.g. analytical thinking, business acumen etc.) skills.

Chapter 8

8.1.1 Planning of the transfer of processes

Whenever the organization identifies the need to transfer a process, the **transfer** requirements **regarding the planning of the transfer of processes** described in this subclause shall be applied and controlled in case of changes (see 8.1.4.2).

Comment: wrong sentence, because this chapter is about planning of transfer of processes, not about transfer requirements

8.1.3.3 Project scope management

Regarding scope management, the project management process shall include:

- a) identification of project requirements (e.g. time, commercial, technical), see 8.2;
- b) definition of the scope of work;
- c) subdivision of work into work packages (e.g. work breakdown structure);
- d) assignment of work packages to work package owners;
- e) verification of work packages.

Regarding scope management, the project management process should include a standardized work breakdown structure.

NOTE Scope management in design and development is detailed in 8.3.2.

Comment: missing requirement since project change management is about changes in scope, time or cost, suggested to add this sentence with similar wording as in 8.1.3.4 and 8.1.3.5

The project organization shall not change the project scope (e.g. work packages, or in case of customer variation orders) unless a change request has been approved (see 8.1.4.2) as defined by the organization

8.1.3.4 Project time management

The project organization shall not change the schedule regarding the customer delivery dates unless a change request has been timely addressed to the customer (see 8.1.4.2)

Comment: Reference included just for clarification

8.1.3.5 Project cost management

Comment: The definition of project budget is done already in the tender calculation of the non-recurring cost. Now, in the project planning the defined budget will be assigned to work packages.

Regarding cost management, the project management process shall include:

- a) ~~definition~~ assignment of the project budget based on calculation from tender;

Comment: The definition of project budget is done already in the tender calculation of the non-recurring cost. Now, in the project planning the defined budget will be assigned to work packages.

- b) the assignment of budget in a cost account structure, considering organizational, ~~statutory and regulatory~~ requirements (e.g. ~~in budget per~~ work packages);

Comment: I don't see the link between the budget assignment in a project and statutory and regulatory requirements. Either this topic needs further explanation (e.g. by a Note) or should be deleted.

- c) a regular control of costs including actual and estimated cost at completion. The project organization should use a software tool for cost tracking.

The project organization shall not increase the project budget unless ~~authorized a change request has been approved~~ (see 8.1.4.2) as defined by the organization.

Comment: better wording to ensure consistency, please see comment in 8.1.3.3

8.1.3.6 Project quality management

Regarding quality management, the organization shall:

- a) establish, implement and maintain a project quality management plan;
- b) ~~establish~~, implement ~~and maintain~~ quality assurance and control activities in the project management process.

8.1.3.9 Project risk and opportunities management

- ii. consider functional and integration maturity levels of the products agreed with the customer as inputs for risks management;

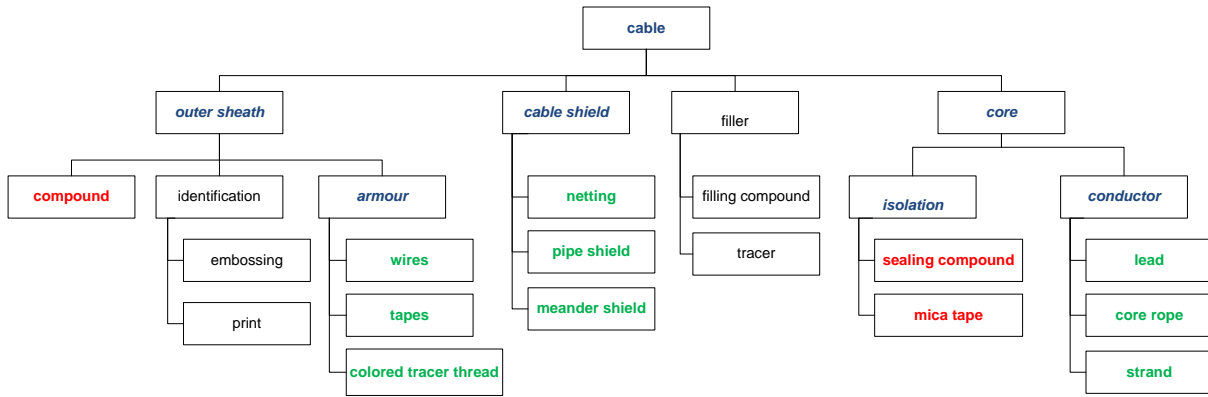
Note: Risk analysis should consider functional maturity including maturity of non-functional requirements, such as performance and other non-functional requirements.

8.1.4.1 General

- b) the product breakdown structure until the lowest ~~replaceable~~ traceable units;



Comment: In many cases configuration items are found below spare part level (LRU). E.g., a cable has no spare parts and is maintenance free, but to trace the safety or functional critical elements of the product breakdown structure, they must go far beyond:



red are safety critical components due to insulating and/or fire-resistant properties
green are functional critical components
due to the required traceability of all safety and functional critical components, all blue marked items must be identified and traced.

In fact, for their configuration control they must trace the chemicals (compounds), conductors, cable shields and armour by batch control. Even the machinery impacts the products. Hence, they must also trace the Extrusion machineries when the cables are produced.

8.1.4.2 Change control

~~NOTE 1 Requirements related to changes are contained in e.g. 8.2.4, 8.3.6, 8.5.6.~~

Comment: this is completely listed in the same section:

For technical changes on products or services, these processes should include in addition the re- evaluation of functional and integration maturity.

Comment: include a new NOTE for better clarification, please see comment in 3.1.3.2.

Note: Re-evaluation should consider functional maturity including maturity of non-functional requirements, such as performance and other non-functional requirements.

The change ~~management~~ control requirements shall apply to:

- p) project management (see 8.1.3);
- q) the requirements for products and services (see 8.2.4);
- r) design and development of products and services (see 8.3.6);
- s) control of externally provided processes, products and services (see 8.4);
- t) production and service provision (see 8.5.6) encompassing production processes, production equipment, production programs (software) and production location.

Comment: editorial proposal to ensure consistence with the terms used in chapter 8.1.4.2.

8.2.2.1 Determining the requirements related to products and services — Supplemental

When determining the requirements, the organization shall consider:

- a) functional and non-functional requirements;
- b) RAMS/LCC requirements;
- c) obsolescence requirements, as applicable (e.g. information coming from market, external providers,

regulations);

d) critical product characteristics as defined by the organization and/or the customer.

e) requirements regarding configuration control, identification and traceability.

.....

I suggest adding one of the most relevant requirements as e)

The organization shall retain documented information according to the previous requirements 8.2.2 a) to b) and 8.2.2.1 a) to ~~b e~~ and, if considered, i. to iii.

8.3.2.1 Design and development planning — Supplemental

In determining the stages and controls for design and development, the organization should consider:

- i. the quality assurance methods for each design and development stage in order to meet the objectives (e.g. defined in a project quality management plan);
- ii. the method to control functional and non-functional requirements;
- iii. the method to control the integration and functional maturity.

Note: Controls should consider functional maturity including maturity of non-functional requirements, such as performance and other non-functional requirements.

8.3.3.1 Design and development inputs — Supplemental

Regarding design and development inputs, the organization shall consider the requirements defined in 8.2.2.1.

In addition, the organization should consider:

- i. production and routine testing requirements, including special processes, so far as the production facilities are known at this stage;
- ii. ~~boundary and interface requirements;~~
- iii. ~~identification, traceability~~ and product preservation requirements.

Comment 1: boundary and interface requirements are integration requirements and hence, already considered as mandatory requirements in 8.2.2.1

Comment 2: Requirements regarding identification and traceability can not be optional design inputs! Therefore, I suggest addressing this in conjunction with configuration control already as mandatory requirements related to products and services in 8.2.2.1 e). So it is covered as well

8.3.4.1 Design and development controls — Supplemental

The organization should apply controls to the design and development process considering:

- i. the functional breakdown;
- ii. the integration and functional maturity;

iii. the implementation of quality assurance methods.

Note: Design controls should consider functional maturity including maturity of non-functional requirements, such as performance and other non-functional requirements.

8.3.4.2 Design reviews

Regarding design reviews, the organization shall define:

a) review criteria ~~for authorization of progression~~ to decide, in design reviews, on acceptance, conditional acceptance or rejection, to authorize progression to the next stage (e.g. ~~checklist, rules~~ criteria for acceptance similar to gate criteria-see 8.1.3.1 e));

Comment 1: I suggest keeping consistency in wording (as in 8.1.3.1 e) to avoid confusion.

Comment 2: Checklists might facilitate design reviews and may contain review criteria, but they do not define review criteria.

8.4.1.1.2 Classification of external providers and external provided products, processes and services

v. the functional and integration maturity of externally provided products (e.g. ready to use).

Note: Classification criteria should consider functional maturity including maturity of non-functional requirements, such as performance and other non-functional requirements.

8.4.1.1.5 External provider offer selection

The analysis should take into account:

- i. the output of a risk analysis;
- ii. the functional and integration maturity of externally provided products.

Note: Provider offer selection should consider functional maturity including maturity of non-functional requirements, such as performance and other non-functional requirements.

8.4.2.2 Externally provided products, processes and services verification after release

Activities for EPPPS verification after release shall include:

a) planning of activities (e.g. in an inspection and test plan, including the determination of the extent, frequency, sample size and methods of control, ~~see 4.4.3~~ applying risk-based thinking (see 0.3.3);

Comment: 4.4.3 doesn't specify the necessary extent and level of controls during incoming goods inspection. Here risk-based thinking applies much more.

The organization shall establish, implement and maintain a plan for periodical verifications of raw material based on risks assessment.

NOTE 1 Verification of raw material composition or compliance could be done by checking e.g. certification, chemical analyses. However, in case of any doubts, the organization should consider re-verification of such analysis by own laboratory tests to identify faked certificates (e.g. in case of buying from traders or when the original source of raw material isn't traceable).

Comment: Checking certificates of conformity is good, but own investigations depending on risk-based thinking are much better. Especially if certificates can't be traced back in a supply chain with many traders of raw materials. We scrapped 40 bogie frames because they've got cracks after 4 years. Our specification was right, the CoCs were faked and not traceable.

8.5.2.1 Identification and traceability — Supplemental

If the status of a product or its ~~identification~~ identity is not known, the organization shall manage the product as a nonconforming product.

Comment: It's more about the missing identity, maybe due to lost identification.

8.5.5.1 Post-delivery activities — Supplemental

The organization shall establish, implement and maintain a process for post-delivery activities. This process shall include:

- a) requirements defined in ISO 9001:2015, 8.5.5;
- b) the control and updating of technical documented information (e.g. operational instructions, maintenance manuals, spare parts list);
- c) problem solving methodology (e.g. 8D, FRACAS, see 8.8);
- d) the approval, control and use of repair instructions;
- e) the provision of spare parts and/or the management of consignment stock, where agreed upon between the customer and the organization;
- f) knowledge of customer complaints as inputs for improving the organization's railway quality management system (e.g. for design and development improvements, production, maintenance activities).
- g) capturing of adequate data to support RAM data collection (e.g. failure symptoms, milage, operating hours, etc. see 8.8.2 c)) and optional also for LCC-data collection (see 8.4.4.iii).

Comment: Proposal to add a very valid requirement: the field data collection. Without having adequate/expressive field data from the demonstration phase or even after warranty, the RAM/LCC calculation is more a guesswork.

8.6.1 Release of products and services — Supplemental

When quantitative measures were taken, inspection and test records shall include actual results data in accordance with the inspection and test instructions.

Comment: in many cases we have qualitative inspections (e.g. visual inspection), were no actual results data exist, only judgement of ok, not ok.

8.8.3 Safety

In case the organization delivers safety-related electrical/electronic/programmable electronic products or services, it shall establish, implement and maintain a process to manage safety activities for products or services. **This process shall include self-designed measuring resources used to verify safety related products or services.** Therefore, the organization shall identify regulations, standards (e.g. IEC 62278, IEC 62425, IEC 62279 or equivalent) or guidelines, which are applicable for safety activities.

Comment: if an organization designs products with e.g. SIL4, and uses self-designed test equipment (internally or externally designed) for verification in production (e.g. for final testing) such measurement resources must be design also in accordance with SIL4 requirements.

8.10 Obsolescence management

The organization shall establish, implement and maintain a process to ensure the availability of the supplied products and spare parts, as contractually required or defined by the organization, as a minimum until end of warranty.

This process shall include:

- a) undertaking obsolescence risk assessment of the product **and all elements of its product structure till lowest replaceable units (spare part level) to be supplied (e.g. by means of a second source strategy or storage approach);**

Comment: second source strategy or storage approach are in rail business not always applicable due to small quantities in contract orders and very long product life. If examples are necessary, I suggest to mention technical upgrade or technical substitution strategies.

- b) **concluding strategies to actively prevent or mitigate obsolescence risks identified,**

Comment: Missing requirement since these strategies are the core of the OMP.

- c) the definition and regular review of an obsolescence management plan for the supplied product **and its spare parts as long as contractually required or defined by the organization;**

Comment: Its not only the product itself what matters, also contractual spares should not be forgotten.

- d) communication with customers.

- e) **communication with external provider (e.g. agreement on an early warning policy or last time buy)**

Comment: Missing requirement because communication with external provider is utmost important to pro-actively manage obsolescence issues.

In addition, this process should define the monitoring of the product portfolio to prevent future **technical, functional and knowledge** obsolescence problems.

Chapter 9

9.1.1.1 Monitoring and measurement — Supplemental

The organization shall identify, establish, implement and maintain documented PIs to monitor and improve the performance of its processes (see 4.4.1 c)), products, services and projects. For further explanation see Annex C.

Annex C: For clarity, the requirement 4.4.1 c) (... monitor and measure the effective operation of a process and to control a process) states that the definition of performance indicators (PIs) is required at least for each process implemented by an organization.

Overview of PIs required or recommended in this document

- PIs listed in 9.1.1.1;
- PIs for implemented processes:
- processes according to Annex A;
- further processes defined as necessary by the organization.

Comment: Provided that process performance measurement shall be balanced between quality, cost and time aspects (e.g., a project is successful when cost-, time- and quality targets are met or exceeded) it is mandatorily required to establish approximately **60 or more PI's** for minimum 20 process. A PI is a cost factor and shall lead to improvements where the benefits are higher than the cost of the index. Who has such high sophisticated ERP systems providing all these PI by pushing the button? SME definitely not! **I suggest focusing PIs on core-processes (tender-, requirements management, design-and development, purchasing, production, after delivery processes) is good enough. Alternatively, you might require a Balanced Score Card from the TOP management. In this case the company installs those PIs which are bringing them further, setting the focus on the right topics to develop their business. This would be a much smarter approach than stupidly saying "all processes".**

9.2.3.1 General

The organization shall establish, implement and maintain a process for internal audits to verify compliance of processes, **projects, products and services** with internal and external requirements.

Comment: the scope if internal audits encompass obviously also critical projects, products and services as mentioned in 9.2.3.2 b). Either all is mentioned, or nothing (delete: processes, projects, products and services since it is listed anyway 9.2.3.2)

9.2.3.3 Auditors management

The organization shall ensure that the audit team auditing the requirements of this document has:

- a) knowledge and skills, maintained and improved (e.g. as a minimum, through regular **internal** refresh trainings), about:

Comment: it should not matter whether a refresher training is internal or external conducted. Especially SMU don't have the resources to prepare, conduct and regularly update its training materials and rely on external support.

- 1) audit principles (e.g. ~~personal~~ **social and individual auditor** behaviour), process and methods;

Comment: Terms proposed are more in line with skills (see 7.2.1)

- 2) the audit scope (e.g. product or service, organizational function);

- 3) relevant clauses of this document according to the audit scope;
- 4) the audit criteria (e.g. internal procedures, this document);

FINISH