INTERNATIONAL RAIL QUALITY BOARD

IRIS Guideline 9: Small and medium-sized enterprises (SMEs)

2021

English

Table of Contents

THIS PAGE LEFT BLANK INTENTIONALLY

1 Introduction

The objective of this guideline is to provide Small and Medium Enterprises (SMEs) with a better understanding of the IRIS® Certification mandatory requirements. Changes in the IRIS certification requirements are excluded. General assumption is that the SME intending IRIS certification has already an established quality management system based on ISO 9001 certified for several years. The guideline focuses on the mandatory requirements for IRIS certification and does not consider recommendations from ISO/TS 22163 for achieving higher maturity levels.

Small and medium-sized enterprises (SMEs) are defined in the EU recommendation 2003/361.

Company category	Staff headcount	Turnover (or)	Balance sheet total
Medium-sized	<250	≤ €50m	≤ €43m
Small	<50	≤ €10m	≤ €10m
Micro	<10	≤ €2m	≤ €2m

Table 1: SME definition

Regarding the activity of an organization ISO/TS 22163 requirements of some complete chapters of the standard can be excluded. If a company has e.g., manufacturing only, the ISO/TS chapters 8.3 and 8.8 can be excluded accordingly. Some items in the IRIS certification assessment sheet can be put as not applicable (N/A) depending on the set-up of an organization. This can e.g., be the case for the requirements of 8.4.2.2 regarding the delegation of verification activities to the external providers (e.g., goods inwards inspection shifted to other suppliers/companies). If there is no delegation the related requirements of 8.4.2.2 regarding the delegation of verification activities to the external providers (e.g., goods inwards inspection shifted to other suppliers/companies). If there is no delegation the related requirements can be put as (N/A).

2 Terms and definitions, abbreviations, symbols

2.1 Terms and definitions

auditee	organization that intends to become IRIS certified
CAR	corrective action request
IAR	improvement action request
FRACAS (Failure Reporting Analysis and Corrective Action System)	closed loop process used to improve dependability of current and future designs by feedback of testing, modification and use experience
IRIS CERTIFICATION® Conformity assessment 2020	rules for achieving and maintaining IRIS Certification® recognition
ISO/TS 22163	"Railway applications – Quality management system – Business management system requirements for rail organizations: ISO

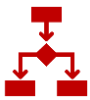
	9001:2015 and particular requirements for application in the rail sector"
LCC (life cycle costing)	process of economic analysis to assess the cost of an item over its life cycle or a portion thereof
process	set of interrelated or interacting activities which transforms inputs into outputs
RAMS (Reliability, Availability, Maintainability, Safety)	ability to perform a specific function and operational reliability, ability to keep a functioning state in the given environment, ability to be timely and easily maintained, ability not to harm people, the environment, or any assets during a whole life cycle
validation	meeting the requirements **for a specific intended use or application**
verification	meeting **specified requirements**

2.2 Abbreviations

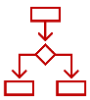
SME	Small and Medium-sized Enterprises according to staff headcount, turnover or balance sheet total.
TS 8.1.3	Chapter from ISO/TS 22163 referred to
CA 11.3	Chapter of IRIS CERTIFICATION® Conformity assessment:2020 made refence to
CA APP 7	Appendix of IRIS CERTIFICATION® Conformity assessment:2020 referred to

2.3 Symbols

K.O. requirement



process mandatory



process recommended

documented information mandatory

documented information recommended

KPI mandatory

KPI recommended

3. Preparation of IRIS certification

To prepare an IRIS certification it is recommended to make oneself familiar with both the content of ISO/TS 22163 and the content of the IRIS Certification Conformity assessment:2020.

In addition, it can be helpful to participate in an IRIS certification training and railway related networks. It is also strongly recommended to visit the IRIS certification website (www.iris-rail.org) or IRQB website (www.irqb-rail.org).

Afterwards it is the best approach to perform a gap analysis based on the assessment sheet in the IRIS-tool. After this analysis, the companies can define in detail the items in the IRIS certification

assessment sheet that can be excluded or set as N/A. After finishing this exercise, the SME has identified the scope that must be covered by the business management system and the weaknesses and can define an action plan to close the gaps. In the following part of the guideline guidance is given how to close gaps related to specific topics e. g. process reviews and contingency planning.

3.1 General

3.1.1 IRIS Certification® scheme

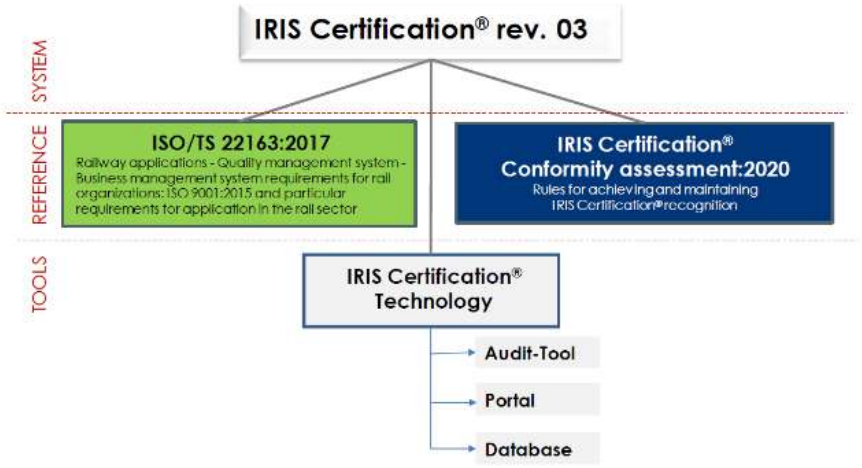


Figure 1: IRIS Certification® set-up

The IRIS certification scheme consists of the ISO/TS 22163:2017 requirements and the IRIS Certification® Conformity assessment:2020 and is supported by the IRIS Certification® Technology (Audit-Tool, Portal and Database). To achieve an IRIS certification, it is mandatory to comply at least with all the applicable requirements from ISO/TS 22163:2017, the assessment sheet and the IRIS Certification® Conformity assessment:2020.

3.1.2 ISO/TS 22163:2017

The ISO/TS 22162 content includes the ISO 9001:2015 content (boxed text) and is extended with rail specific requirements (marked either as “Supplemental” (e. g. 7.2.1 Competence – Supplemental) or described in additional chapters (e. g. 8.1.3 Project management, 8.9 First article inspection)).

Whenever the standard refers to “shall” this is related to a mandatory requirement. All “should” refer to recommendations to achieve a higher maturity level of the quality management system. When intending the first IRIS certification it is the recommendation to the auditee to focus on meeting the “shall” requirements.

After this the focus can be set on additional "should" recommendations.

3.1.3 IRIS Certification® Conformity assessment:2020

The IRIS Certification® Conformity assessment:2020 describes the assessment methodology, the certification process as well as additional requirements. Especially the scoring methodology and rules regarding the certification structure (remote locations & site extensions) are very useful and important information for the auditee. These will be applied by the IRIS auditors during the assessment.

3.1.3 IRIS Certification® Technology

Auditees intending to be IRIS certified must take the following steps:

1. register their organization in the IRIS portal (https://www.iris-rail.org) as a member
2. select a certification body that will audit the organization
3. If needed, purchase the IRIS-audit tool.

The audit-tool is a software that supports the IRIS auditors during their assessment. It contains e.g., the readiness review, the assessment sheet, the process performance evaluation, and the customer perception evaluation. The tool can support the organization to understand the audit approach.

For SMEs it is not mandatory to purchase an IRIS tool, but it might be helpful to have direct access to the information. It is sufficient if an organization owns one IRIS audit tool per site.

If the auditee chooses “Advanced registration” during registering in the portal this includes one audit-tool license. This can be used by the auditee to prepare its organization (e.g., performing the gap analysis).

3.2 Requirements ISO/TS 22163

3.2.1 Determining the scope of the quality management system (TS 4.4.3)

The hierarchical structure of the processes of a quality management system can be documented e.g., in a simple process landscape:

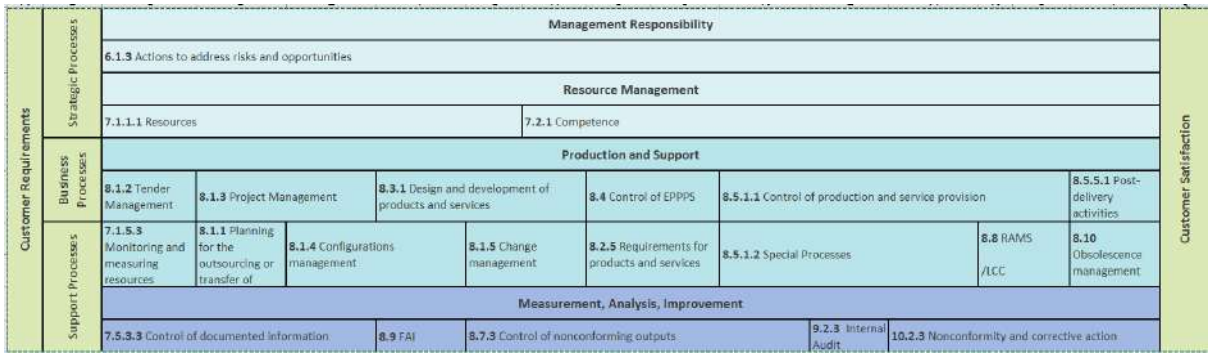


Figure 2: Example process landscape

3.2.2 Safety policy/safety objectives (TS 5.2.4)

The safety policy required is related to **product safety** and not to health, safety, and environment. Safety objectives are also related to product safety and can be e. g. closure of safety issues raised by the customer within 48 hours, reduction of minor safety issues by 20% compared to the previous reporting period, reduce the number of recalls due to safety issues by 20% or reduce electrical accidents by 30%.
This applies to all organizations, even if the organizations have no design and development function, because activities in manufacturing and maintenance also influence the product safety.

3.2.3 Processes, process owners and process reviews (TS 5.3.3, TS 9.4, CA APP 5, CA APP 6 performance evaluation template)

ISO/TS 22163 requires 22 documented processes including 5 processes for process performance evaluation (highlighted).

Figure 3: Mandatory processes

Turtle Diagram:

A simple approach to document the mandatory processes is the turtle diagram. This supports organizations to have a complete overview of the process on one page. For the processes project management (8.1.3), requirements management (8.2), control of EPPPS (8.4), design and development (8.3) and production and service provision (8.5) (depending on the IRIS Certification activity design and development or production and service provision can be excluded by the auditee) it is highly recommended to document the processes in the turtle format.

Figure 4: Example turtle diagram project management

Figure 5: Example turtle diagram requirements management

It is recommended that the auditee defines only performance indicators in the turtle diagrams for those processes where the ISO/TS 22163 requires one or more KPI (see also CA APP 8, ISO/TS 9.1.1.1).

Process Owner:

For each of the mandatory processes a process owner must be appointed and empowered. To assure process owners are independent from the process execution but familiar with the process it is useful to appoint e.g., the deputy of the responsible manager as a process owner. In small organizations it is possible that one person is process owner for different processes.

3.2.4 Contingency planning (TS 6.1.4)

A contingency planning must be established based on the evaluation of the business risk. This can cover e.g., labour shortages, failure of key production equipment or succession planning. The contingency plan can be documented in a simple Excel format (see example below).

		Probability (Likelihood)		
		1	2	3
Impact (Consequence)	1	LOW 1	LOW 2	MEDIUM 3
	2	LOW 2	MEDIUM 4	HIGH 6
	3	MEDIUM 3	HIGH 6	HIGH 9

Contingency Plan

Submitted by: Date submitted:

Reviewed by: Date reviewed:

ID	Event	Likelihood	Impact	Score	Solution to deal with event	Responsible
		LOW / MEDIUM / HIGH				
1	Equipment breakdown	2	3	6	Inform supervisor of the shift. A first repar approach is given by supervisor and operators. Supervisor informs to maintencance in case of an unrepairable breakdown	Mr. Xing. Tel. 176 879 4444 xing@example.com
2	Missing parts in production line due to not any material in stock	1	2	2	Material handler informs to supervisor about the missing parts. A special transport from supplier is done (safety stock)	Mr. Müller. Tel. 176 879 3333 müller@example.com
3	Quality problems in production	1	2	2	Inform supervisor in order to ask for temporarily approvals if possible.	Mr. Müller. Tel. 176 879 3333 müller@example.com
4	Rejected parts in final lines of production	1	3	3	Receiving inspection makes rework temporarily in order to not stop production	Mr. Müller. Tel. 176 879 3333 müller@example.com
5	Lack of skilled labor willing to relocate	2	2	4	Combination of incentives and benefits of the job rotation program	Mr. Müller. Tel. 176 879 3333 müller@example.com
6	Labor shortages	2	3	6	See HR Program about potential interns to be hired	Mr. Blanc Tel. 176 879 2222 blanc@example.com
7	..	..	..	..	..	..

Figure 6: Example contingency plan

It is recommended to review (and update if necessary) the contingency planning on an annual basis, e.g., during the management review. Additionally, it is recommended to "test" the planning e.g., simulate a machinery break down and transfer the machining to the selected external provider.

3.2.5 Business planning (TS 6.4)

It is not necessary to create an additional documented information called “Business Plan” for the IRIS certification. It is acceptable that the information required in TS 6.4 for business planning are defined in different documents, depending on organization-structure of the auditee’s organization. During the audit, the auditee shall be able to show evidence regarding the requirements.

3.2.6 Monitoring and measuring resources (TS 7.1.5.3)

It is important that the required process shall also cover production tools for special processes (e.g., torque wrenches, crimping tools, welding machines, thermocouples, so on). The calibration interval can be adapted. Criteria for the calibration interval can be e.g., criticality of the task to be performed with the tool, frequency of use, manufacturers specifications etc.

For the handling of special processes, the IRQB guideline 6 SPECIAL PROCESSES (https://www.irqb.org/publications) gives guidance.

The organization shall make sure that the record of measuring contains unique identification (e.g., ID Number) of the measuring resource and date of the measuring. This can e.g., be assured by specifying these requirements in the defined template to be filled during the inspection.

Assure that tool identification and measuring date are part of the documented information.

Inspection Report

Customer	
Supplier	

Test performed according:	VDA Norm	
Reson for the test:		Initial Inspection
		Change request
		Other

Drawing			
Part Number			
Material			
Order ID			
Process			
Machine ID			
Inspection date			

Part Characteristics					Inspection / Test Result				Other
ID	Qty	Feature	Requirement (in mm)	Tolerance (in mm)	Result	Correct / Incorrect	Measurement Tool Type	Measurement Tool ID	Notes
B.1	1	Diameter	4,5	±0,5	4,8		Gage Pin	MT 532	
B.2	1	Diameter	5,5	±0,5	5,5		Gage Pin	MT 007	
...									
...									
...									

Peformed by		
Date		
Siganture		

Figure 7: Example quality record

3.2.7 Organizational knowledge/Competence (TS 7.1.6.1, TS7.2.1)

The knowledge of the organization and the competence of the employees have a key influence on the management system and its processes. Therefore, it is important for SMEs to determine the knowledge and competences required for process execution and to check them against the existing knowledge and competencies.

A simple matrix with a rating system (e.g., traffic light) can be used for the analysis and documentation. If gaps in knowledge and competences are identified, appropriate measures (e.g., obtaining additional information, external training, training on the job etc.) should be taken to close the gaps.

Competency matrix

Knowledge/competence	Process A		Process B		Product a		Product b		Process C		Process D		Product c		Product d	
Employee	target	actual	target	actual	target	actual	target	actual	target	actual	target	actual	target	actual	target	actual
Employee 1																
Employee 2	Oct-21		Nov-21		Dec-21				Feb-22		Jan-22		Dec-21			
Employee 3					Jan-22								Nov-21			
Employee 4																
Employee 4																
...																
...																

... Expert
... general knowledge
... no knowledge
... not necessary

Figure 8: Example competence matrix

The assessment should be repeated at regular intervals, e.g., during the annual management review or appraisal interviews.

3.2.8 Control of documented information (TS 7.5.3.3)

To assure that all required retained documented information (CA APP 8) is available the auditee can create an overview list that covers the requirements (e.g., type of documented information, person creating, person approving, retention period). It is recommended to review (and update if necessary) the list on an annual basis, e.g., during the management review.

Chapter	Description	Example	Create/Approve	Identification	Distribution	Filing	Retention period
4.4.2	quality management system and its processes						
5.3.1	Organizational roles, responsibilities and authorities - supplemental	list of process owners	quality manager/ site general manager	issue date	management team	issue date	10 years
6.1.3	actions to address risks and opportunities - supplemental	risk register	process owner/ site general manager	issue date	management team	issue date	10 years
7.1.1.1	resources - general - supplemental						
7.1.5.1	monitoring and measuring resources - general	gauge capability	quality assurance/ quality manager	consecutive number	quality planning	consecutive number	-
7.1.5.2	measurement traceability	assessment of previous measurements	quality assurance/ engineering	consecutive number	quality department	consecutive number	20 years
7.1.5.3	monitoring and measuring resources - supplemental	register of monitoring and measuring equipment	quality assurance	consecutive number	quality department	consecutive number	20 years
7.2	competence	competence matrix	team lead	staff number	-	staff number	5 years
7.2.1	competence - supplemental						
7.5.3.2	control of documented information						
7.5.3.3	control of documented information - supplemental						
8.1.1	planning for the outsourcing or transfer of processes	transfer plan	project manager/site general manager	project name and issue date	project team, management team	project name and issue date	10 years
8.1.2	tender management						
8.1.3	project management						
8.1.3.8	project risk and opportunity management	risk and opportunity register	project manager/ project director	issue date	project team, management team	issue date	20 years
8.1.4	configuration management						
8.1.5	change management						
8.2.2							
8.2.3.2	review of requirements related to products and services						
8.3.2.1							
8.3.3	design and development inputs						
8.3.3.1	design and development inputs - supplemental						
8.3.4	design and development controls						
8.3.4.2	design reviews						
8.3.4.3	design verification						
8.3.4.4	design validation						
8.3.5	design and development outputs						
8.3.6	design and development changes						
8.4.1	control of externally provided processes, products and services						
8.4.1.1	control of externally provided processes, products and services - general - supplemental						

Figure 9: Example table for mandatory retained information

3.2.9 Planning for the outsourcing or transfer of processes (TS 8.1.1)

A process transfer is the outsourcing of a (sub)process out of strategic or, for example, capacity reasons. It is also often used to manage load peaks or bottle necks.

Examples for the transfer of processes can be e.g., painting, machining, sandblasting process steps or warehouse and packaging. Transfer of processes can cause additional risks, which can have impacts on products and services quality. Because the supplier/ outsourcing might not be familiar with detailed elements of the relative internal processes in the organization. To avoid unnecessary loss in quality, cost, and time, it is very important to perform feasibility and risk analysis at a very early stage of the planning. Through the analysis potential impacts can be identified by using the following checklist:

Transfer Plan									
System / Equipment :				Part number and index :					
				New manufacturer unit/supplier (NM) :					
Nr.	Items	Required		Conform		Starting date	End date	Responsible	Remark
		Yes	No	Yes	No				
Transfer management									
1	Feasibilty study	X							
2	Customer autorisation	X							
3	Audit before transfer done at Bombardier	X							
4	Bombardier autorisation	X							
5	Detailed planning of the transfer process	X							
6	Open issue list at Bombardier available	X							
7	Modifications issued throughout transfer listed	X							
8	Pending non-conformities listed	X							
9	Configuration management available	X							
Preparation management									
10	Manufacturing equipment available at NM	X							
11	Components and tools needed for manufacturing are available	X							
12	Technical documents needed for manufacturing available and if necessary translated at NM	X							
13	Industrial documents needed for manufacturing available and if necessary translated at NM	X							
14	Quality documents needed for manufacturing available and if necessary translated at NM	X							
15	Open issue list at NM started	X							
16	New suppliers file validated	X							
17	Purchasing modifications mastered (suppliers, incoming, ..)	X							
18	Logistic modifications mastered (delivery, packaging,schedule, ...)	X							
19	Contingency stock defined and achieved	X							
Process management									
20	NM workers trained and qualified on new products or processes	X							
21	Special processes are transfered (welding, painting, crimping, heat treatment, ...)	X							
22	Training on special process done	X							
23	Special processes are mastered and qualified	X							
24	First equipment manufactured at NM	X							
25	Type test to performed according list of tests	X							
Supplier validation									
26	FAI at NM carried out by Bombardier	X							
27	Audit to the NM processes carried out by Bombardier	X							
28	Corrective Actions Plan (to FAI / audit of Bombardier) sent by NM to Bombardier	X							
29	Corrective actions derived from FAI / audit done by Bombardier are under control	X							
30	Authorisation for Manufacturing of series sent by Bombardier	X							
Customer validation									
31	FAI at NM carried out by customer	X							
32	Audit to the NM processes carried out by customer	X							
33	Corrective Actions Plan (to FAI / audit of Client) sent by NM to customer and Bombardier	X							
34	Corrective actions derived from FAI / audit done by customer are under control	X							
35	Authorisation for manufacturing of series sent by customer	X							
Reliability evidences									
36	Incoming inspection level at Bombardier adapted to NM product quality level	X							
37	Q & D product performance checked in NM (no recurrent non-conformity)	X							

	Written by	Verified by		Customer approval (when applicable)
Position			Company	
Name			Name	
Date			Date	
Signature			Signature	

Figure 10: Example transfer plan

3.2.10 Project management (TS 8.1.3)

For the handling of project management requirements, the IRQB Guideline 10 Project Management (https://www.irqb.org/publications) gives guidance.

3.2.11 Configuration management (TS 8.1.4)

For traceability reasons or the proper handling of customer claims it is essential that an SME defines at least for the safety related items the criteria for identification (e.g., serial numbers, batch numbers). Additionally, it is important to document e.g., in a simple list which part was assembled into which product. Configuration management is applicable to both, soft- and hardware.

3.2.12 Change management (TS 8.1.5)

According to TS 8.1.5 the change management process is not only applicable to technical product or service changes. In addition to this it is also applicable for project management, requirements management, design and development, EPPPS and production and service provision. This must be considered by the auditee when establishing the process.

It is recommended to use Change Identification Numbers (CR Number) to track changes through the whole supply chain. Change management applies also to production documents (Working Instruction, drawing, quality inspection….).

Before implementation of a change, it is recommended to identify which steps, e.g., documents, tools of production will be touched by the change.

During implementation of the change: remove old revision drawing from production line. Make record of change date and batch number of first products with the CR Number.

Following list could be used for register and track Change Requite.

Change Management Register

				Application to departments teams							Implementation and date						
Change request						Production							Production			Supplies	
CR number	CR topic	CR number of customer	Date	R&D	EN	Tools	Areas	Documents, drawings, inspection plan	Suppliers	Logistics	R&D	EN	Tools	Areas	Documents, drawings, inspection plan	Batch Nr. of first product	Logistic
2021-001	Change of material XY to material XZ DWG 789-546	-	01.02.2021		x			x				05.02.2021			05.02.2021	DN753	
2021-002																	
2021-003																	

Figure 11: Example change management register

3.2.13 Requirements for products and services

The requirements management process is applicable for design and development of new products or services, tender management, project or order execution and change control.

The application of requirements management can be classified in two groups:

WITHOUT design and development responsibility

- Main focus on customer specification with customer requirements as well as statutory and regulatory requirements
- It has to be ensured that the organization has the capability to fulfil the customer requirements within procurement, order execution, production and testing

WITH design and development responsibility

- Main focus on customer requirements, statutory and regulatory requirements, requirements resulting from market analysis as well as experience from similar products, tenders and projects as well as complaints
- Requirements need to be evaluated before starting the D&D process

It is highly recommended to implement a standardized tool or checklist (e.g., Excel tool, database (e.g., DOORS, Polarion Requirements…)). Requirements can be managed for example by a requirements traceability matrix (see figure 12: Example of a requirements traceability matrix). It is emphasized to collect the requirements of standard products or services listed in a standard matrix for an efficient requirements management. Project or order specific additional requirements should be added to the matrix for an overall requirement processing.

Requirements traceability matrix

Project name: ABC Project number: 12345

Project manager: Mr. XY Status: 08.02.2021

ID	Requirements cluster	Object type	Headline	Requirement original	Requirement	Evaluation	Comment	Responsible	Status	Influence on req. ID	Solution	Technical Specification	System / Component
1	Technical	Heading	1 Painting			compliant	Compliant with a different solution	Mr. XY					
2	Technical	Requirement	1.1 Corrosion resistance	corrosion resistance for 25 years		compliant		Mr. XY	closed	#1	Paint XY, layer thickness x µm, pre-treatment degreasing & sandblasting	Painting specification	Component YX
3	Technical	Information				non-compliant		Mr. XY	open				
4	Commercial	Information	Penalties	In case of not fulfilling the delivery schedule a penalty of XX is due.				Mr. XY		#15			
5	Quality	Requirement	2. Identification	Components XY have to be identified by a unique identification code		compliant with risk		Mr. XY			Use of serialization with unique QR code		
6	Quality	Requirement	3. Testing	Rubber metal parts need to fulfil requirements regarding hysteresis as defined in specification XXX		compliant		Mr. XY				Specification XXX	
7	Quality	Requirement	4. Documentation	all 3.1 certificates must be handed over electronically		compliant		Mr. XY					
8	Environmental, health & safety							Mr. XY					
9	legal							Mr. XY					
10	homologation							Mr. XY					
11	Management	Requirement	5. Deliveries	Deliveries need to be in accordance to delivery plan		compliant		Mr. XY	closed		Delivery plan is aligned with production capacity, material availability etc.		
12	..	..	..	..	..	..	..	..	..	..	..	..	..

Figure 12: Example of a requirements traceability matrix

Following there are examples of requirements, which should be considered, listed:

- Customer requirements (commercial, technical, LCC and quality requirements, …)
- Environmental, health and safety (EHS) requirements
- Requirements, which result of the state of the art (e.g., standards…)
- Legal requirements including homologation
- Requirements for the intended use (sometimes this is not specified by the customer)
- Requirements, which result of self-commitments (e.g., no child labor, …)
- Requirements, which result of market analysis
- Obsolescent requirements

The processing of the requirements can be done according to the following process and documented in the requirements traceability matrix:

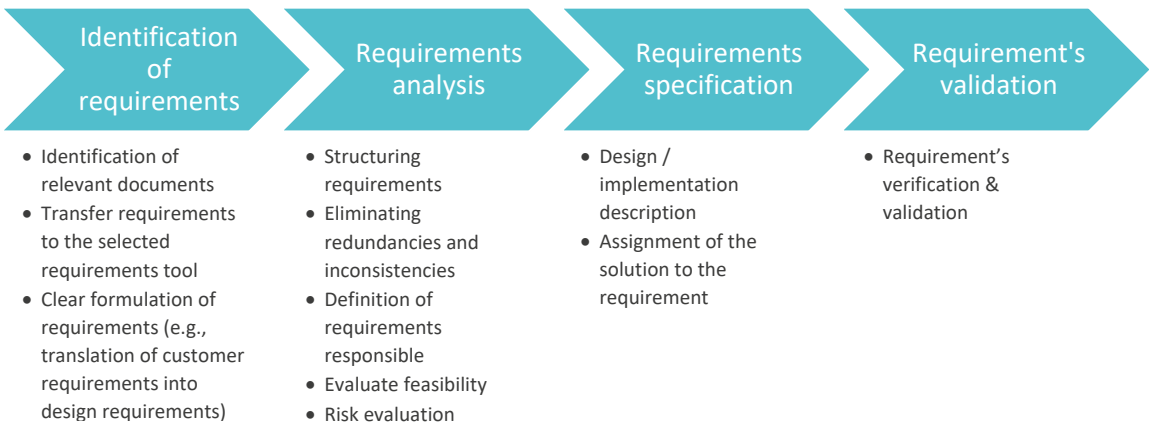


Figure 13: Example of requirements management process

It is important, that the evaluation of the requirements is performed by well experienced and trained staff. Required competencies and knowledge can be defined in role descriptions for requirements manager or requirements engineers.

The evaluated requirements should be aligned with the customers on a regular basis. Especially it should be focused on the requirements, which are non-compliant or compliant with risk.

The overall target of the requirements management is to reduce financial risks due to not fulfilment of requirements.

3.2.14 Design and Development of products and services (TS 8.3)

In case the organization has no design and development activity for railway industry, the chapter TS 8.3 is excluded.

If chapter TS 8.3 is applicable it is recommended to check whether other standards are already in place (e. g. CENELEC) and if the requirements are already fulfilled.

The following diagram shows a typical cycle of design & development control (TS 8.3.4): design review, verification, and validation.

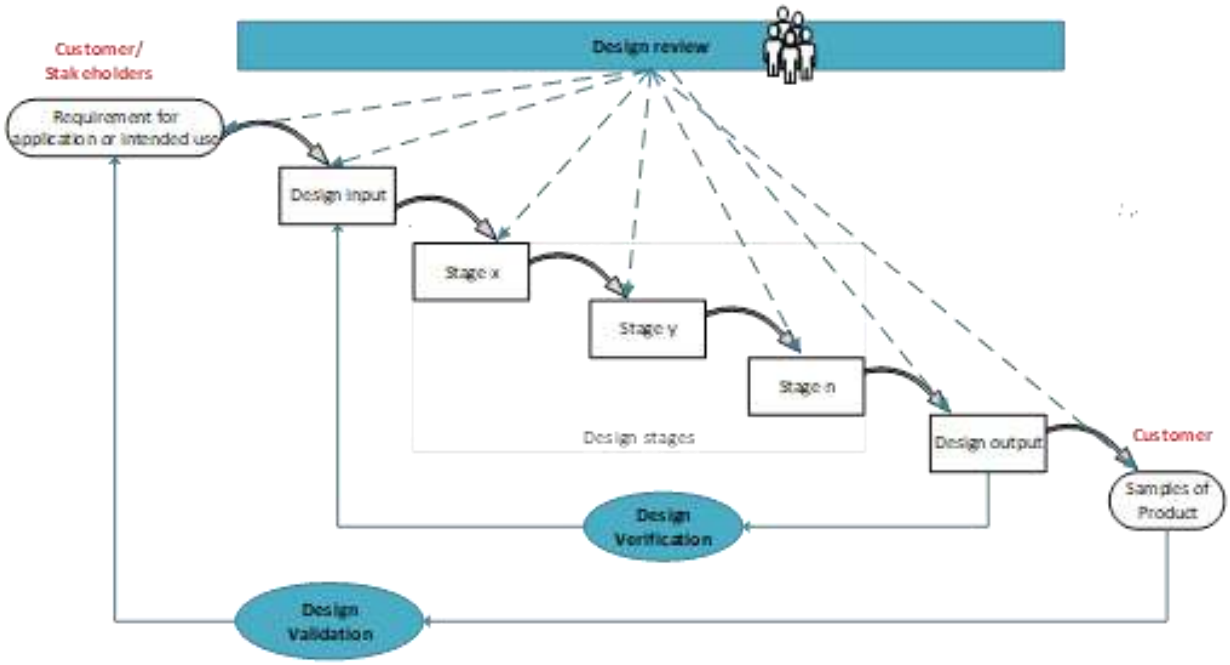


Figure 14: Cycle of design & development control

- The matrix below is a summary comparing design review, design verification and validation

Design Control	Purpose	When	What	By whom	Method					Output
Design Review	Evaluate the ability of results of design stages, for release to next stage	During duration of design according to planning	Assessing status of defined objectives, activities, schedule based on criteria & requirements. Identification of risks and additional actions	Independent Panel	can be performed by the means of discussion with checklist, comparisons (Shall vs IST) and auditing					Authorization of progression to next stage and actions when necessary
Design Verification	Ensure/ confirmation the outputs of design& development meet the input requirements	At particular design stages. E.g., when results achieved by design	Design data, objective models, prototype	Design team and independent person, e.g., design manager	Analysis e.g., finite element analysis	Calculation Demonstration	Mock-up	Test Proof testing Prototype testing	Inspection	Documented information of the confirmation E.g., Test report Actions when necessary
Design Validation	Ensure the product, service meet requirement of application or needs of the user	At stage of product/service achieved by design and after completing the verification	Samples of proposed products	Design team and independent person, e.g., design manager	Analysis e.g., a comparison to other validated models and simulations or previous test result	Demonstration for basic confirmation of performance capability	Qualification test	Test e.g., Type test to validate functional performance	Product approval test	Documented information. E.g., Type test report, Conformation from customer

Table 2: Summary and comparison of design review, design verification and validation

3.2.15 Control of EPPPS (TS 8.4)

A documented process for external provided products, processes, and services (Supplier management) is mandatory (e.g., a turtle diagram, management handbook, flow charts) but with minimum content of TS 8.4.1.1 a-k).

Classification of external suppliers: Classification of external providers and EPPPS is basis to define the type and extent of control to external providers and EPPPS.

For example, if a classification in A, B and C suppliers is applied, the type and extent of control of an A supplier is much more intense than for a C supplier.

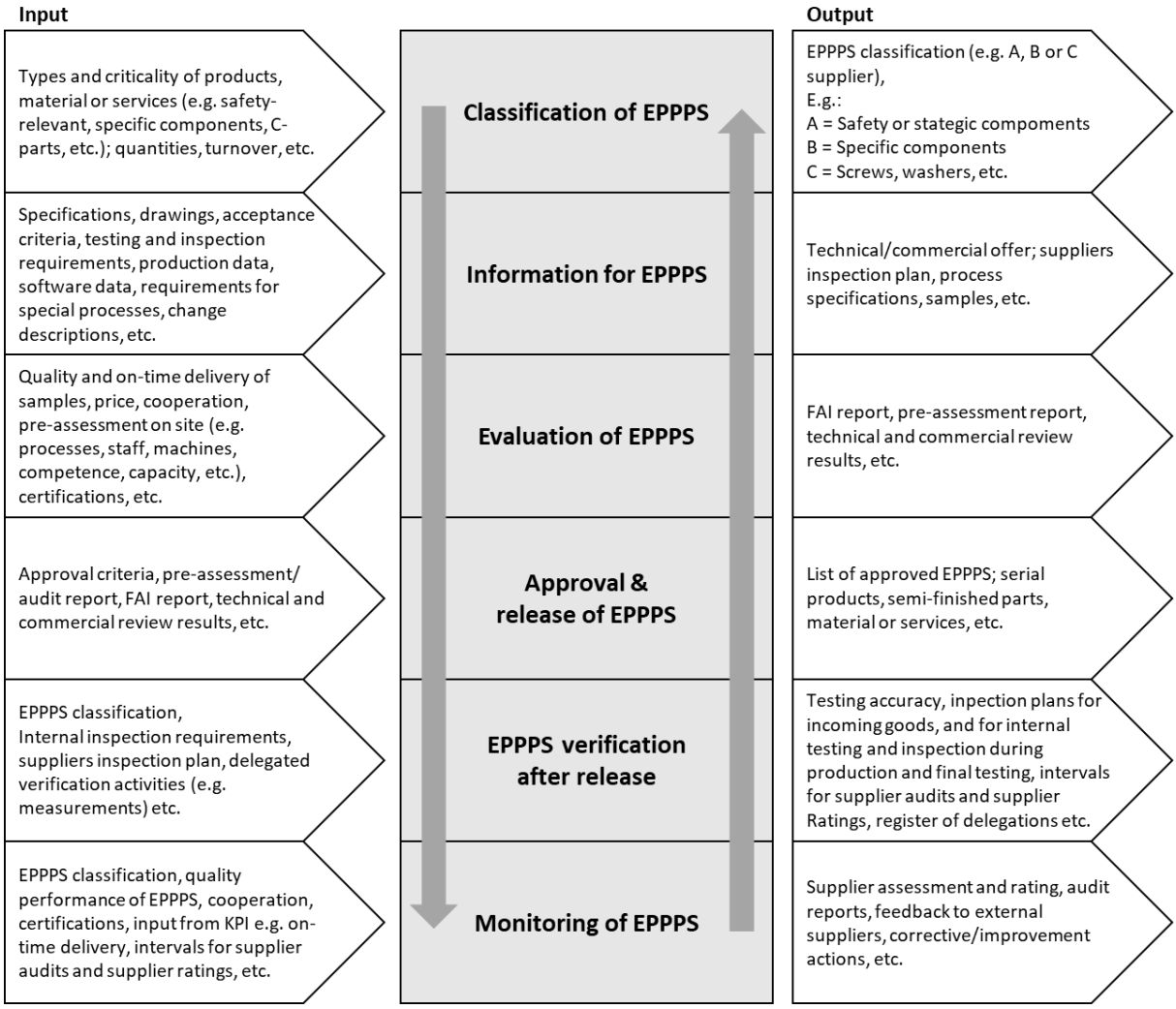
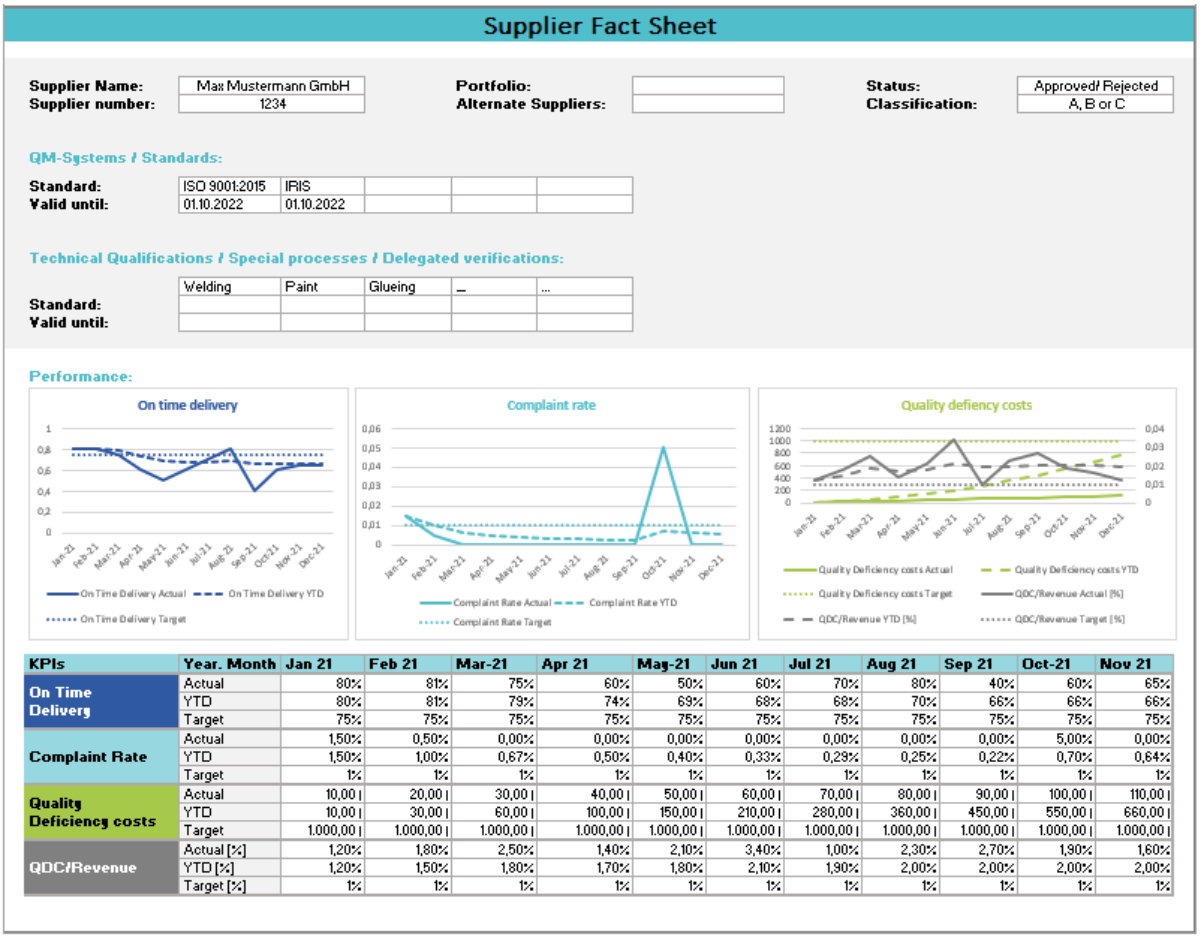


Figure 15: Control of EPPPS

For the evaluation of external suppliers, a strategy needs to be established, implemented, maintained and monitored that all suppliers comply to ISO 9001, ISO/TS 22163 or other similar quality management systems.

The supplier evaluation can be done with a supplier fact sheet (see example). The Supplier Fact Sheet should be reviewed regularly.



Supplier Fact Sheet

Supplier Name:	Max Mustermann GmbH	**Portfolio:**		**Status:**	Approved/ Rejected
Supplier number:	1234	**Alternate Suppliers:**		**Classification:**	A, B or C

QM-Systems / Standards:

Standard:	ISO 9001:2015	IRIS			
Valid until:	01.10.2022	01.10.2022			

Technical Qualifications / Special processes / Delegated verifications:

	Welding	Paint	Glueing	_	...
Standard:					
Valid until:					

Performance:

KPIs	Year. Month	Jan 21	Feb 21	Mar-21	Apr 21	May-21	Jun 21	Jul 21	Aug 21	Sep 21	Oct-21	Nov 21
On Time Delivery	Actual	80%	81%	75%	60%	50%	60%	70%	80%	40%	60%	65%
	YTD	80%	81%	79%	74%	69%	68%	68%	70%	66%	66%	66%
	Target	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
Complaint Rate	Actual	1,50%	0,50%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	5,00%	0,00%
	YTD	1,50%	1,00%	0,67%	0,50%	0,40%	0,33%	0,29%	0,25%	0,22%	0,70%	0,64%
	Target	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Quality Deficiency costs	Actual	10,00	20,00	30,00	40,00	50,00	60,00	70,00	80,00	90,00	100,00	110,00
	YTD	10,00	30,00	60,00	100,00	150,00	210,00	280,00	360,00	450,00	550,00	660,00
	Target	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00	1.000,00
QDC/Revenue	Actual [%]	1,20%	1,80%	2,50%	1,40%	2,10%	3,40%	1,00%	2,30%	2,70%	1,90%	1,60%
	YTD [%]	1,20%	1,50%	1,80%	1,70%	1,80%	2,10%	1,90%	2,00%	2,00%	2,00%	2,00%
	Target [%]	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%

Figure 16: Example Supplier fact sheet

3.2.16 Production and service provision (TS 8.5)

Preparation for production release

Those responsible for production should check the necessary conditions for trouble-free production before the start of production. The following topics should be considered:

Topic	Responsible	yes	no	Remarks
Are there development requirements for production available and clear? (Product specification, test specification, labelling, traceability etc.)	Development /Construction			
Has the hardware design been approved?	Development /Construction			
Has the product master data been created (item number, version etc.)?	Development /Construction			
Is there approved production data (parts lists, hardware data, software data, drawings, etc.) available?	Development /Construction			
Has the First Article Inspection of the procurement items been successfully passed?	Quality Assurance			
Is the required material available in sufficient quantity?	Procurement			
Are storage quantities and restocking time fixed with suppliers?	Procurement			
Are approved inspection scopes as well as inspection plans for the incoming goods inspection available?	Quality Assurance			

Are the necessary storage capacities available?	Warehouse			
Has the product and production process FMEA been completed?	Quality Assurance			
Are the required workplaces, machines, equipment, devices available?	Production Planning			
Are approved machine programmes available?	Production Planning			
Has the capability of machines and devices been demonstrated?	Production Planning			
Are maintenance plans and maintenance instructions in place?	Maintenance			
Is the manufacturing instruction available?	Production Planning			
Are the process specifications for special processes ready?	Production Planning			
Do the employees have the necessary competence to manufacture the product?	Production Planning			
Is a sufficient initial production quantity defined to demonstrate process capability?	Production Planning			
Is a capable testing device available and has it been approved?	Production Planning			
Is there an approved test scope and test procedure?	Production Planning			
Are plans and instructions for the monitoring of test equipment available?	Maintenance			
Has the product packaging been defined and is it available?	Warehouse / Logistics			
Has a production order been scheduled?	Production Planning			

Table 3: Example production readiness

Production equipment

In addition to the ISO 9001 the ISO/TS 22163 focuses on the availability and the readiness of production equipment such as:

- Machines, tooling, moulds etc.
- Tools
- Gauges
- Jig
- Etc.

This includes any device necessary to produce the product on the shopfloor.

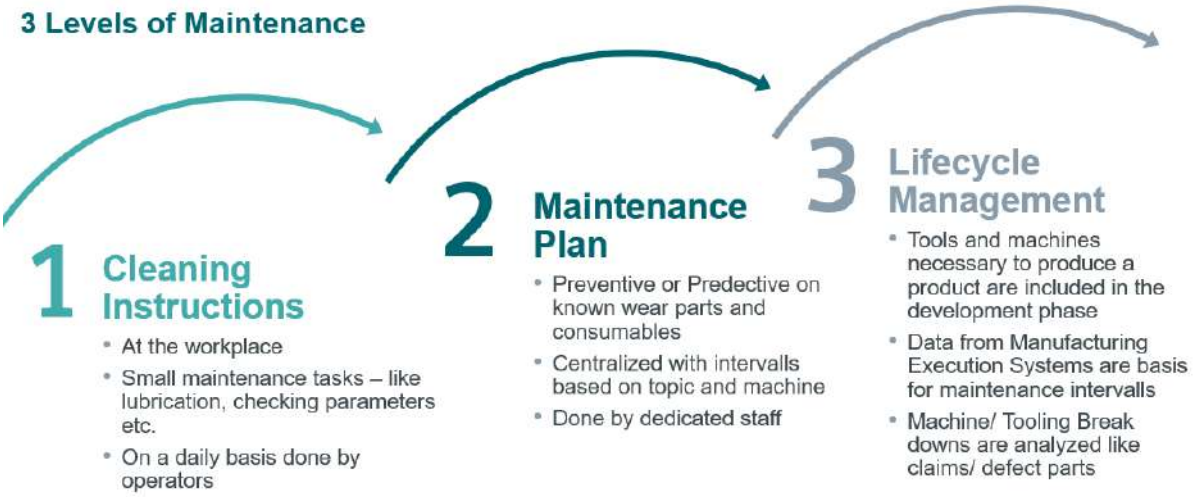


Figure 17: Levels of maintenance

Please check the examples given in the supporting documents for maintenance plans/ instructions, checklists, and machine/tooling history.

Preservation

Regarding preservation ISO/TS22163 requires a documented specification that covers all conditions related to preservation that have an impact on the product conformity including storage, internal processing, and delivery to the customer. If there are no customer requirements it is recommended that an organization does an analysis and defines the internal preservation standard by considering the five below mentioned topics:

Topic	Example	Samples:
Marking and labelling (identification)	Definition of label; marking of lifting points, stamping of serial numbers, attachment of certificates, hazard labelling	
Special handling (sensitive products)	Use of protective nets to avoid damage during transport, use of rubber coated lifting gears, use of product specific transport racks, ESD packaging	
Cleaning/storage	Avoid degassing of hazardous material, deletion of machining chips	
Shelf-life control/ stock rotation	Paint, glue, stored parts that need defined movement (e.g., hydraulic components, stored bogies), hoses	
Environmental condition	Temperature, humidity, sunlight, cleanliness, Shipping and special packaging (e.g., sea freight)	

Table 4: Examples preservation

It is recommended that the product related measures taken by the organization are summarized in a table that is regularly checked and updated when there is a need.

3.2.17 Special processes (TS 8.5.1.2)

For the handling of special processes requirements, the IRQB guideline 6 SPECIAL PROCESSES (https://www.irqb.org/publications) provides guidance.

3.2.18 Post-delivery activities (TS 8.5.5.1)

Post-delivery activities are defined as after handover to the customer, until contract obligations end. Due to this the definition of post-delivery activities are not limited to customer service activities. They can cover e. g. updating of technical documentation, administration of repair instructions or spare part management. As for post-delivery activities when a process is mandatory the requirements cannot be put as not applicable. To reduce the number of processes, the organisation may cover the requirements related to post-delivery activities in other process descriptions e. g. customer requirements in 8.2 Requirements for products and services or the approval and control of repair instructions in 7.5 Documented information or in 8.1.5 Change management.

3.2.19 Release of products and services (TS 8.6)

To release products and services an organization shall define testing activities along the production flow. A manufacturing quality control helps organizations to fulfil the requirements of the ISO/TS.

Manufacturing Quality Control Plan

Quality Control Plan Number:	ABC 001	Product Number:	12345	Product Name:	XY	Contact:	Mr. XY
Document Revision:	A1	Release Date:	08.02.2021	Status:	Serial Production		

Process Step	Process Name	No.	Characterisric	Technique	Reference Documents / Drawings	Specification / Nominal	Measuring unit	Upper Tolerance	Lower Tolerance	Evaluation / Measurement Equipment	Quantity	Frequency	Control Method	Reaction Plan	Test record
1	Process 1	1	Surface	visual	DWG 123	without visible burr and stains	N/A				10%	per lot	Sampling	Rework / Scrap	Record 123
		2	Length XY	measure	DWG 123	11,5	cm	11,1	11,9	Vernier caliper	5%	per lot	Sampling	Rework / Scrap	Record 123
		3													Record 123
		4	Tensile	destructive	ISO 6892, DWG 123	RM	N/mm²			Tensile testing maschine XY			Sampling	Scrap	Record 123
2	Process 2	1	Lengh YZ	measure	DWG 456		cm			CMM 12, Programm XYZ					Record 234
		2		measure										Return to suppl	Record 234
		3													Record 234
3	Process 3	1	XY	function	SPEC 123		N/A				100%	per lot	Full check	Rework	
		2													
		3													
		4													
		5													

Figure 18: Example manufacturing quality control plan

Organizations need to consider, that the test records shall include actual results data (see chapter TS 8.6) and the used measurement devices (see chapter TS 7.1.5.3).

3.2.20 Control of nonconforming outputs (TS 8.7)

A process to manage nonconforming outputs shall be implemented. This process can be combined with the requirements of TS 10.2 nonconformity and corrective action.

It is essential to apply this process to nonconforming outputs of the EPPPS process, nonconforming production outputs as well as nonconforming products or services, which have been detected while delivery or post-delivery.

It is required to record nonconforming outputs and concessions. It is highly recommended to implement a standardized tool (e. g. Excel tool, database, …) to manage nonconforming outputs including root cause analysis and corrective actions (e.g., 8D method, 5 Why, Ishikawa diagram etc.). Examples for problem solving methods can be found in the IRQB guideline 7 Problem solving.

Examples for problem solving methods can be found in the IRQB guideline 7 Problem solving.

The measurement and analysis of the following KPIs is the basis of the continuous improvement process:

- TS 9.1.1.1 i) nonconformities raised by the customer
- TS 9.1.1.1 j) internal nonconformities
- TS 9.1.1.1 k) external providers' nonconformities

Examples for the KPI definition can be found in the IRQB guideline 3 KEY PERFORMANCE INDICATORS (KPI) (https://www.irqb.org/publications).

Examples for problem solving methods can be found in the IRQB guideline 7 PROBLEM SOLVING (https://www.irqb.org/publications).

3.2.21 RAMS/LCC (TS 8.8)

First it is recommended that the SME checks if chapter 8.8 is applicable for its organization, e. g for companies with pure production and/or maintenance activities this K.O. requirement can be excluded.

Second it is recommended to check whether other standards are already in place (e. g. CENELEC) and are or can be applied.

Thirdly the IRQB guideline 4 RAMS/LCC can be used toobtain some guidance.

3.2.22 First article inspection (TS 8.9)

First article inspection (FAI) is a process for release, following points must be considered:

1. This process covers not only release of products, also verification and release of related production equipment (including machine, new fixtures, tools...) and production processes.
2. Generally, three types FAIs are applicable for a company:
   - customer required FAI → normally leaded by customer
   - internal FAI for internal release → leaded by organization self
   - FAI of procured parts/ components/ systems → normally leaded by organization self or is delegated to third-party.
3. Internal FAI is an effective approach to minimis risks of failure from customer FAI.

The table below is a summarized overview of three types of FAIs

FAI process apply to	Conditions	Required by whom	Who	What	Output
Products made by <u>suppliers/ outsourcing</u> of organization	first production at new supplier	Organization	Supplier and Organization	• inspection of product. • inspection of production documents of critical processes and special processes • verification of quality inspection and results. • verification of fixture/ tools of critical & special processes. • verification of parameters of production machines (critical processes). • considering requirements of customer's FAI. • a standard checklist should be used for FAI. See sample below.	• FAI report with clear result. See ISO TS 22163 clause 8.9 d). • released production including new fixtures/ new tools in case of condition release/ release. • corrective actions in case of condition release/ rejection.
	new product for existing supplier	Organization	Supplier & organization or supplier		
	new production line for existing product/ new machine/ new fixtures…				
	new location of existing supplier				
	re-starting after long time break of existing product				
	major technical change				
Products made by <u>organization self</u>	new product	Organization	Organization		
	major technical change				
	new production line/ technology / new machine / new fixtures				
	new location of existing production line/ products				
Required by <u>customer</u>	defined by customer	Customer	Customer and organization	• customer requirements. • preparation according to customer requirement.	• Decision by customer. • Actions when required.

Table 5: Types of FAIs

First Article Inspection

Document Nr.

FAI Typ

	Product 1
	Product 2
	Product 3

FAI Reason

	New Supplier		Change production sequence
	Changed Design		Production Interruption
	Repeated Inspection		New or Changed Part
	New Manufacturing		Other

Participants

Name	Signature	Name	Signature

Serial Production

	Released
	Released with condition
	Blocked

Confirmation

We declare that:	1. The shown samples were produces with serial tools and under serial conditions
	2. The FAI and description in this report were made correctly in all conscience, deviations were registered and resolved before delivery

	Date	Name	Signature
Responsible 1			
Responsible 2			
Responsible 3			
Responsible 4			

Reviewed material / system / component

Article Number	ID	Drawing and description	Revision	Quantity	Serial number	Manufacturing date
...						
...						

Co-applicable Documens

Identification Nr.	Document	Drawing	Date	Comments

FAI Performed by	
Date	
Signature	

Created by	
Checked by	
Approved by	
Revision	
Date	

Distribution list	

Figure 19: Example FAI report

3.2.23 Obsolescence management (TS 8.10)

IEC 62402:2019 describes obsolescence in the following way: “Obsolescence might be because production has ended or because of the lack of availability of service provision, support of software or processed material.”

Purpose of obsolescence management is to ensure availability of supplied products for the customer until end of warranty or contractual agreement. It applies not only to electronic products, also to other types of products as well, and even software. It is applicable to all kinds of products, services and production equipment covering e.g., drawing, datasheet, standard, written specification or a list of keywords and properties. A specification cancelled or an item’s approval to a withdrawn specification can also cause obsolescence.[1]

Activities to overcome obsolescence issues can be: Second source strategy, storage approach, form-fit-function compatibility approach (new revisions of parts can replace previous versions) etc.

3.2.24 Performance management (TS 9.1.1.1)

For the handling of the performance evaluation the IRQB guideline 3 KEY PERFORMANCE INDICATORS (KPI) (https://www.irqb.org/publications) gives guidance. For SME it is proposed to always choose the example 1 from ANNEX 1 (as it is the modest and easiest one). If possible, the auditee should limit the number of used KPI to the mandatory ones from TS 9.1.1.1 (customer satisfaction, customer on time delivery, nonconformities raised by the customer, internal nonconformities, external providers’ nonconformities, external providers on time delivery, quality deficiency costs, project costs, requirements management process, design and development process). It might also be possible to use the same KPI to measure the performance of different processes.

3.2.25 Audit programme, auditors management (TS 9.2.3)

The audit program must include the processes and critical projects, products and services and must cover all production shifts. The processes must be audited at least once in 3 years (by considering the status and importance of the audit scope). To reduce the internal effort, it is recommended to create a 3-year audit planning (to be updated once a year) that lists the involved functions, the IRIS topics to be audited, critical projects and products, the planned date, and the involved auditors (see example below). To conduct a product audit, product related checkpoints of the FAI checklist can be used.

[1] IEC 62402:2019

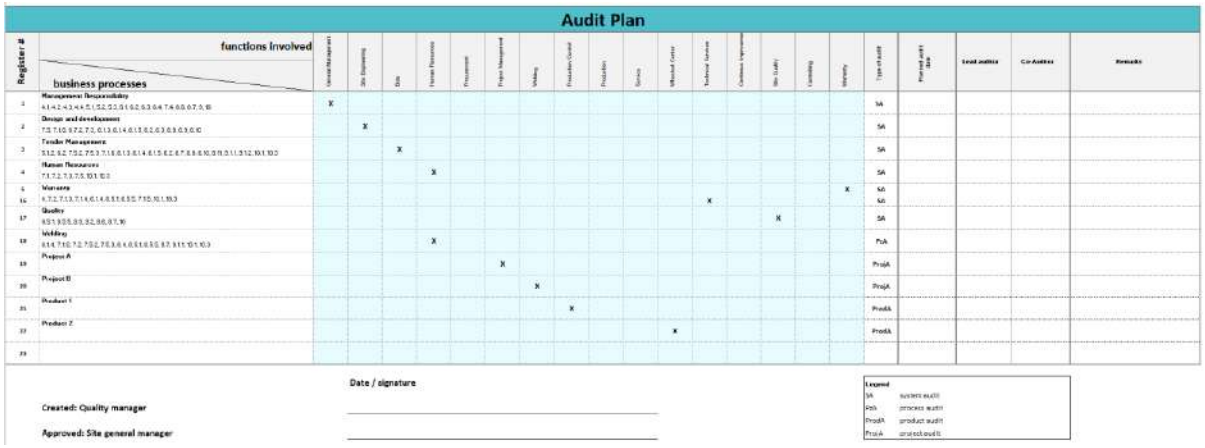


Figure 20: Example audit program

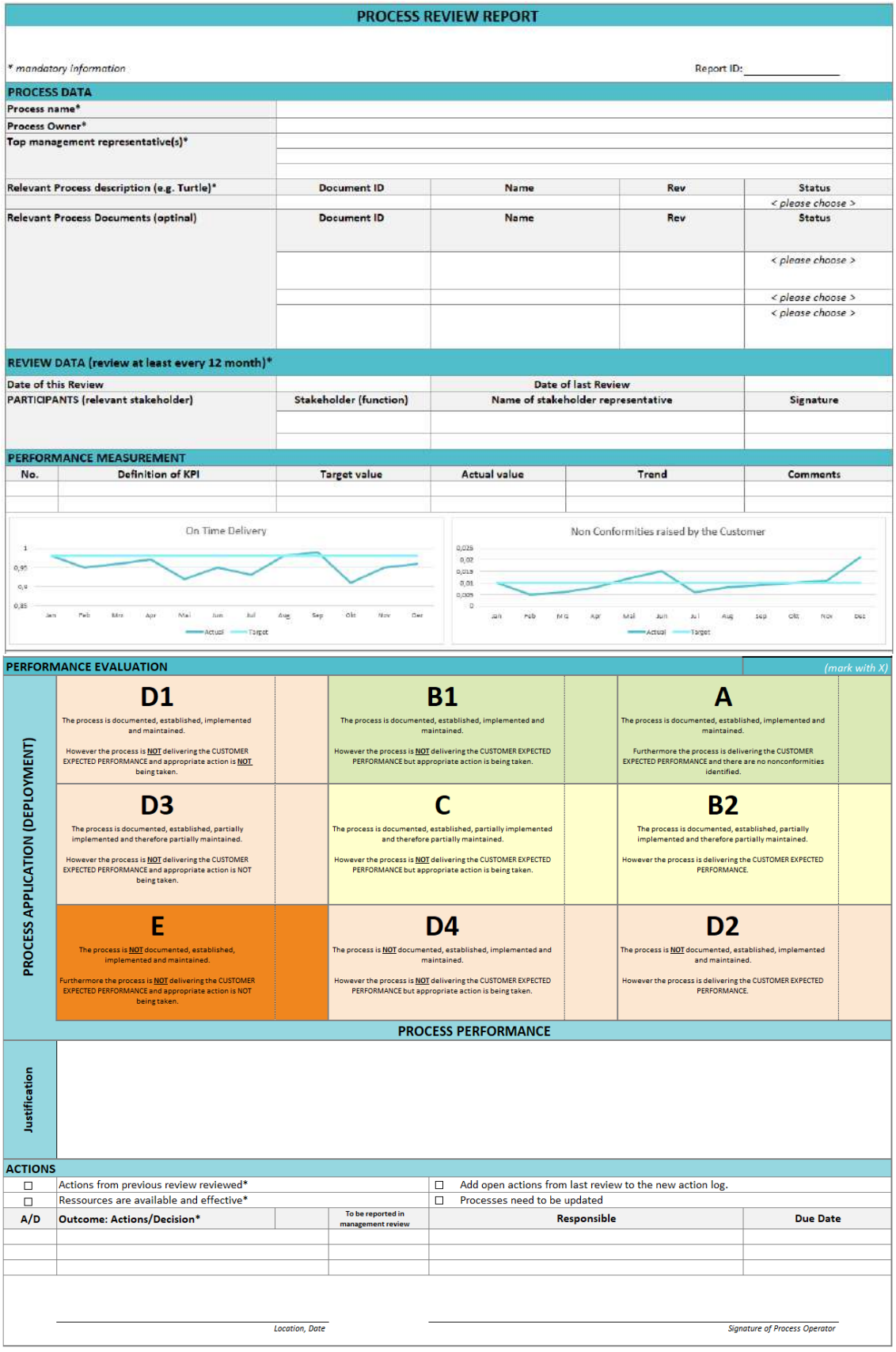
3.2.26 Process reviews (TS 9.4)

For each of the 22 mandatory processes a process review must be performed and documented on an annual basis. This should give the organization the possibility to get an internal overview of the process performance and to address selected results of the reviews as an input for the management review. It can also highlight whether:

- actions of previous process reviews are closed
- a change of the process description is necessary
- an update of the risks and opportunities is necessary
- additional resources are needed
- decisions and actions need to be taken and monitored

It is also possible to combine the process reviews of some related processes to be more effective (e.g., configuration management and change management).

To assure that all requirements from ISO/TS 22163 chapter 9.4 are met it is recommended to use the turtle diagram and a defined form based on performance evaluation template in the IRIS Certification Conformity assessment:2020. The following template can be used to perform the process reviews. All items marked with * are mandatory to fulfil the requirements of ISO/TS 22163 and all additional items are optional.



PROCESS REVIEW REPORT

* *mandatory information*

Report ID: _____

PROCESS DATA				
Process name*				
Process Owner*				
Top management representative(s)*				
Relevant Process description (e.g. Turtle)*	Document ID	Name	Rev	Status
				< please choose >
Relevant Process Documents (optinal)	Document ID	Name	Rev	Status
				< please choose >
				< please choose >
				< please choose >

REVIEW DATA (review at least every 12 month)*			
Date of this Review		Date of last Review	
PARTICIPANTS (relevant stakeholder)	Stakeholder (function)	Name of stakeholder representative	Signature

PERFORMANCE MEASUREMENT					
No.	Definition of KPI	Target value	Actual value	Trend	Comments

PERFORMANCE EVALUATION *(mark with X)*

PROCESS APPLICATION (DEPLOYMENT)

D1 The process is documented, established, implemented and maintained. However the process is NOT delivering the CUSTOMER EXPECTED PERFORMANCE and appropriate action is NOT being taken.	**B1** The process is documented, established, implemented and maintained. However the process is NOT delivering the CUSTOMER EXPECTED PERFORMANCE but appropriate action is being taken.	**A** The process is documented, established, implemented and maintained. Furthermore the process is delivering the CUSTOMER EXPECTED PERFORMANCE and there are no nonconformities identified.
D3 The process is documented, established, partially implemented and therefore partially maintained. However the process is NOT delivering the CUSTOMER EXPECTED PERFORMANCE and appropriate action is NOT being taken.	**C** The process is documented, established, partially implemented and therefore partially maintained. However the process is NOT delivering the CUSTOMER EXPECTED PERFORMANCE but appropriate action is being taken.	**B2** The process is documented, established, partially implemented and therefore partially maintained. However the process is delivering the CUSTOMER EXPECTED PERFORMANCE.
E The process is NOT documented, established, implemented and maintained. Furthermore the process is NOT delivering the CUSTOMER EXPECTED PERFORMANCE and appropriate action is NOT being taken.	**D4** The process is NOT documented, established, implemented and maintained. However the process is NOT delivering the CUSTOMER EXPECTED PERFORMANCE but appropriate action is being taken.	**D2** The process is NOT documented, established, implemented and maintained. However the process is delivering the CUSTOMER EXPECTED PERFORMANCE.

PROCESS PERFORMANCE

Justification

ACTIONS				
☐	Actions from previous review reviewed*		☐	Add open actions from last review to the new action log.
☐	Ressources are available and effective*		☐	Processes need to be updated
A/D	Outcome: Actions/Decision*	To be reported in management review	Responsible	Due Date

_____ *Location, Date*

_____ *Signature of Process Operator*

Figure 21: Example process review template

It must be assured that the process review cover and the related record documents meet the requirements mentioned in the assessment sheet in item 9.4-1.

To assess the effectiveness of the process it is recommended to apply the matrix for performance evaluation from IRIS Certification Conformity assessment:2020:

PROCESS APPLICATION			
	The process is documented, established, implemented and maintained as per ISO/TS 22163 requirements. However the process is **NOT** delivering the **CUSTOMER EXPECTED PERFORMANCE** and appropriate action is **NOT** being taken.	The process is documented, established, implemented and maintained as per ISO/TS 22163 requirements. However the process is **NOT** delivering the **CUSTOMER EXPECTED PERFORMANCE** but appropriate action is being taken.	The process is documented, established, implemented and maintained as per ISO/TS 22163 requirements. Furthermore the process is delivering the **CUSTOMER EXPECTED PERFORMANCE** and there are no nonconformities identified.
	The process is documented, established, **PARTIALLY** implemented and **THEREFORE PARTIALLY** maintained as per ISO/TS 22163 requirements. However the process is **NOT** delivering the **CUSTOMER EXPECTED PERFORMANCE** and appropriate action is **NOT** being taken.	The process is documented, established, **PARTIALLY** implemented and **THEREFORE PARTIALLY** maintained as per ISO/TS 22163 requirements.. However the process is **NOT** delivering the **CUSTOMER EXPECTED PERFORMANCE** but appropriate action is being taken.	The process is documented, established, **PARTIALLY** implemented and **THEREFORE PARTIALLY** maintained as per ISO/TS 22163 requirements. However the process is delivering the **CUSTOMER EXPECTED PERFORMANCE**.
	The process is **NOT** documented, established, implemented and maintained as per ISO/TS 22163 requirements.. Furthermore the process is **NOT** delivering the **CUSTOMER EXPECTED PERFORMANCE** and appropriate action is **NOT** being taken.	The process is **NOT** documented, established, implemented and maintained as per ISO/TS 22163 requirements. However the process is **NOT** delivering the **CUSTOMER EXPECTED PERFORMANCE** but, appropriate action is being taken.	The process is **NOT** documented, established, implemented and maintained as per ISO/TS 22163 requirements. However the process is delivering the **CUSTOMER EXPECTED PERFORMANCE**.
	PROCESS PERFORMANCE		

Figure 22: Matrix for performance evaluation

This table allows to assess the process regarding process application and process performance. Process application is defined as the grade a process is documented, established, implemented, and performed (full, partially, and not). The process performance is assessed as the grade the customer expected performance is met and if appropriate action is taken. Customer expected performance is not necessarily in line with the internal expected performance of the auditee's organization (e.g., an increase of the on-time delivery from 51% to 60% might be a large improvement for the auditees organization but this might still be far away from the customer expected on-time delivery performance of 98%). This must be taken into consideration for the process performance assessment. It is recommended to use the trend of the mandatory KPI for the last period/since the last process review for the review. The auditee is asked to assure that the KPIs used for the performance assessment are the same as documented in the turtle diagrams.

As selected results from process reviews are inputs for the management review, process reviews cannot be part of the management review.

3.3 Requirements IRIS Certification® Conformity assessment:2020

3.3.1 Scope of IRIS certification and application (CA 1, CA 5.1, CA APP 1)

IRIS certification is possible for organizations providing design and development and/or manufacturing and/or maintenance of products for the rail sector. Depending on the auditees business one or more scopes from the table can be chosen as scope of certification:

No.	IRIS Certification* description	EN 15380-2 MPG designation
01	Vehicle body	B
02	Vehicle fitting out	C
03	Guidance	E
04	Power system, drive unit	F
05	Auxiliary systems	H M Q
06	Braking system	R
07	Interiors	D
08	Control apparatus for train operations	G
09	Passenger Information Systems (PIS)	P
10	Communication, monitoring and safety equipment	J
11	Carrier systems, enclosures	T
12	Electrical wiring	U
13	Doors, entrances	N
14	Heating, Ventilating and Air Conditioning (HVAC)	L
15	Lighting	K
16	Vehicle linkage devices	S
17	Rolling stock	-
18	Infrastructure	-
19	Single rail components	-
20	Components related to special process work	-

Figure 23: Scope of certification

3.3.2 Audit and certification cycle (CA 4.1, CA APP 2)

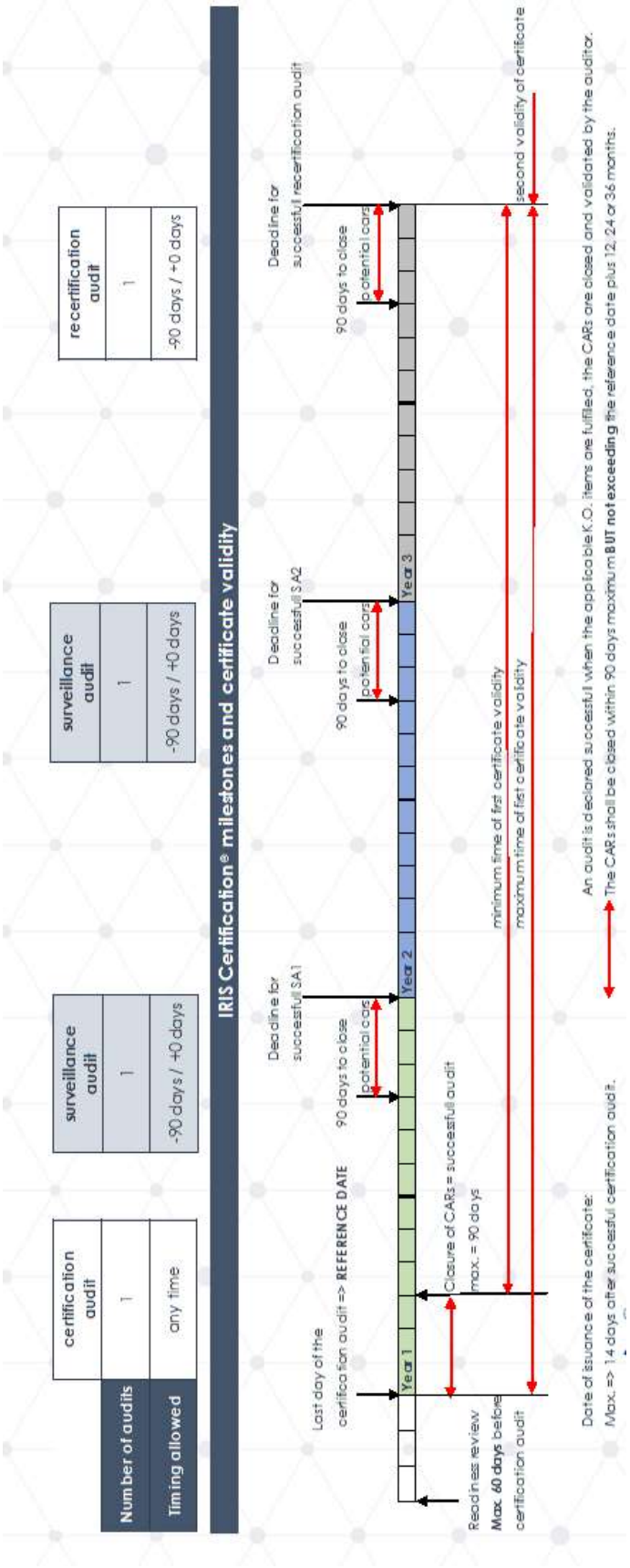


Figure 24: Relation audit and certification cycle

3.3.3 Readiness review (CA 5.4)

The readiness review is a mandatory process in an IRIS certification. During the review, the IRIS auditor assesses the auditees readiness to proceed with the IRIS certification. It is recommended to perform the readiness review with sufficient time before the intended audit (max. 60 days in advance) to provide the auditee the possibility to make corrections in case of a failed readiness review. During the readiness review the applicable K.O. requirements are pre-assessed in detail. This must be considered by the auditee during the preparation.

3.3.4 Supporting activities (CA 5.8, CA APP 3)

Before starting the preparation of the IRIS certification by the auditee it is necessary to define the set-up of the organization to be audited. IRIS certification applies a single site certification. A matrix certification is not possible. It is possible to integrate remote functions on remote locations (e.g., design, sales, logistics, purchasing and warehouse) and site extensions (manufacturing and/or maintenance activities belonging to the connected certified site) in the IRIS certificate. The set-up has an influence on the IRIS audit sequence and frequency.

3.3.5 Information required for the audit planning/data package (CA 10.1)

To assure a good preparation of the IRIS audit the auditee is required to send the following documents to the IRIS auditor (60 calendar days before the audit): stakeholder analysis, customer perception data, turtle diagrams for the processes with process performance evaluation and a list of the auditees processes and their interactions.

3.3.6 Scoring methodology (enablers, process performance, customer perception) (CA 13.1, CA APP 4, CA APP 6)

3.3.6.1 Enablers

No.:	Defined:	Qualified:	Optimized:	Example:
6.1.2-2	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. (1)	CLOSED ITEM		(1) NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an op-portunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, open-ing new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.
6.1.3	Actions to address risks and opportunities – Supplemental			
6.1.3-1 KO KO	The organization shall establish, implement and maintain a documented risk management process.			
6.1.3-2	This process shall consider: a) the requirements described in 6.1.1 and 6.1.2; b) regular review and update of risks and actions; c) retention of documented information from risk assessments, reviews and actions. (1)	Plus: In addition, this process should: i. involve customer and external providers in joint work on risk assessment and response; ii. require a multidisciplinary approach for risk reviews; and iii. evaluate its effectiveness based on QDCs. OPEN ITEM	Plus: Lessons learned and best practices are taken into account to improve the risk management process.	(1) NOTE 1 FMEA can be applied for managing risks in business planning, design and development, projects or production. NOTE 2 FMECA can be applied for managing risks of critical functions or items (e.g. safety-related).

Figure 25: Example assessment sheet

To assess the maturity level of the quality management system the IRIS auditor uses an assessment sheet (part of the audit-tool). The assessment sheet contains K.O items, closed items and open items. To assure a first IRIS certification it is mandatory for the auditee to meet all applicable K.O and closed items and to achieve at least the level defined in the open items.

3.3.6.2 Process performance

Additionally, the IRIS auditor performs an assessment during the IRIS audit for the following mandatory key processes: project management, requirements management, control of EPPPS, design and development and production and service provision (depending on the IRIS Certification activity design and development or production and service provision can be excluded by the auditee). The assessment is performed based on the turtle diagrams (see 3.2.3), the KPIs (see 3.2.24) and the matrix for the performance evaluation (see 3.2.26).

3.3.6.3 Customer perception

Evaluation part	ISO/TS 22163 requirement	Method to be used	Weighting Factor
Stakeholder analysis	4.1, 4.2, 6.4	5 open questions	x 1.5
Customer feedback	5.1.2, 8.2.1.1, 9.1.2, 9.1.2.1	5 open questions	x 2.5
KPIs: - Customer satisfaction - Customer on-time delivery - Nonconformities raised by the customer	9.1.1.1 g)- i)	KPI evaluation matrix	x 2.0

Table 6: Detailed customer perception assessment

The third pillar of the IRIS auditor assessment is the evaluation of the customer perception. The IRIS auditor performs this based on two mini assessment sheets regarding customer feedback and stakeholder analysis and additionally the mandatory KPIs customer satisfaction, nonconformities raised by the customer and on-time delivery are evaluated based on the matrix for KPI evaluation.

E	D	C	B	A
The KPI is not completely documented, established, implemented and maintaines as per ISO/TS 22163 requirements 9.1.1.1 a) to f).	The KPI is documented, established, implemented and maintained as per ISO/TS 22163 requirements 9.1.1.1 a) to f). However the KPI is **NOT regularly** indicating the **EXPECTED PERFORMANCE** and appropriate action is NOT being taken.	The KPI is documented, established, implemented and maintained as per ISO/TS 22163 requirements 9.1.1.1 a) to f). However the KPI is **NOT regularly** indicating the **EXPECTED PERFORMANCE** and appropriate action is being taken.	The KPI is documented, established, implemented and maintained as per ISO/TS 22163 requirements 9.1.1.1 a) to f). Furthermore the KPI is **regularly** indicating the **EXPECTED PERFORMANCE** though it cannot be demonstrated that this performance is in line with **CUSTOMER EXPECTED RESULTS.**	The KPI is documented, established, implemented and maintained as per ISO/TS 22163 requirements 9.1.1.1 a) to f). Furthermore the KPI is **regularly** indicating the **EXPECTED PERFORMANCE** and it can be demonstrated that this performance is in line with **CUSTOMER EXPECTED RESULTS.**
KPI EVALUATION MATRIX				

Figure 26: Matrix for KPI evaluation

3.3.7 Nonconformity management (CA 14)

Compliance	Maturity Level	Points	Action Open Items	Action Closed Items	Action K.O. Items
Compliant	optimized	4	No specific action expected	-	-
	qualified	3	Improvement action might be recommended	-	-
	defined	2	Improvement action as per auditor´s request	No specific action expected	-
Non Compliant	poor	1	Corrective action mandatory; to be closed within 90 days	-	-
	insufficient	0	Corrective action mandatory; to be reaudited within 90 days	Corrective action mandatory; to be reaudited within 90 days	Corrective action mandatory; to be reaudited within 90 days

Table 7: Corrective and improvement actions

Depending on the results of the scoring of the enablers nonconformity management must be applied by the auditee for scores poor (1 point) or insufficient (0 points). For raised CARs scored 1 it is the responsibility of the auditee to close these within 90 calendar days documentary (including the analysis of the root cause, definition and implementation of corrective actions and assessment of effectiveness). For CARs scored 0 the same methodology must be applied by the auditee and the IRIS auditor has to re-audit on-site within 90 calendar days.

To assure continuous improvement of the quality management system the IRIS auditor is asked to define IARs (agreed with the auditee) regarding the achievement of a higher maturity level regarding defined open items in the assessment sheet. IARs shall be closed by the auditee before the next audit.

3.3.8 Knock-out (K.O) requirements (CA APP 7)

During the readiness review the IRIS auditor performs a detailed pre-assessment of the knock-out requirements as their fulfilment is essential for organizations in the rail industry. It is important for the auditee to have these properly understood and prepared.

CA APP 7 defines 10 K.O. requirements. Depending on the business of the auditee max. 3 of them can be excluded (see list below).

K.O. Requirement Number	Applicability	Clause	Requirement
1	Always applicable	6.1.3	**Actions to address risks and opportunities — Supplemental** The organization shall establish, implement and maintain a documented risk management process.
2	Always applicable	7.2.1	**Competence — Supplemental** The organization shall retain documented information related to competence management activities.
3	Always applicable	8.1.3	**Project management** The organization shall establish, implement and maintain a documented process to manage projects. NOTE 1 The scope of the project management process depends on the business model of an organization. In most of the rail sector companies it is from tender phase until the end of warranty period. However, in other cases it can be limited to design and development only (e.g. for the development of a new product family or platform).
4	Always applicable	8.1.4	**Configuration management** The organization shall establish, implement and maintain a documented configuration management process appropriate to the product. NOTE 1 The configuration management process is applicable for hardware and software.
5	Always applicable	8.1.5	**Change management** The organization shall establish, implement and maintain documented processes to manage changes.
6	Always applicable	8.2.5	**Requirements for products and services — Supplemental** The organization shall establish, implement and maintain a documented process to manage requirements.
7	Always applicable	8.4.1.1	**General — Supplemental** The organization shall establish, implement and maintain a documented process for externally provided processes, products and services (EPPPS) described in 8.4.1 to ensure conformity to requirements.
8	Can be put as not applicable	8.5.1.2	**Special processes** The organization shall establish, implement and maintain a documented process for the management of special processes.
9	Can be put as not applicable	8.8	**RAMS / LCC** The organization shall establish, implement and maintain documented processes to manage RAM / LCC
10	Can be put as not applicable	8.9	**First article inspection** The organization shall establish, implement and maintain a documented process for first article inspection

Figure 27: K.O. requirements

ANNEXES

All supporting documents are available for download in an editable format by clicking here

THIS PAGE LEFT BLANK INTENTIONALLY