INTERNATIONAL COMPETENCE CENTRE RAIL GmbH



The "HIGH SCHOOL" for IRIS ADVANCED IRIS competence level 3 of 4

The best way to update your IRIS knowledge to Rev.04 and to expand for GOLD/SILVER

(ISO/FDIS 22163:2022 & IRIS Certification® Conformity Assessment:2020)



ENGLISH Version (August 2023)

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Color code blue: flowcharts, showing the requirements of the respective chapter in context.

READ SAMPLE

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Color code blue:

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Color code blue: flowcharts, showing the requirements of the respective chapter in context.

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Your feedback email (after the course) will include a download-link including

editable templates:

- 1. Gate/Design Reviews
- 2. Good Practices Template
- 3. Lessons Learnt Database
- 4. Process Review Template
- 5. Project Change Template

as well as editable good examples, ready to use:

- **11.** Requirements management (doors)
- 12. Record retention schedule
- 13. BSC Meeting Preparation Questions
- 14. CDRL (for bid phase)
- **15.** Classification schemes (customers, material, suppliers)
- 16. Customer Data Entry Sheet
- 17. Customer satisfaction in projects
- **18.** Customer satisfaction index
- 19. Master document classes
- 20. Business continuity plan
- 21. PPPA Release Planning (Mountain Bike)

- 6. Test plan ITP
- 7. Legal Repository
- 8. SIPOC & FMEA Template
- 9. Techn. Change Template
- 10. Internal audit report
- 22. Product architecture (eBike)
- 23. Project WBS &. NRC -Calculation
- 24. Responsibilities of process owners
- 25. Stakeholder analysis (external audit)
- 26. Project mandate sheet
- 27. Checklist Cerfitificate of Conformity
- 28. Balanced Score Card
- 29. Auditor skills / knowldge
- 30. Requirements to archive rooms
- 31. QDC Instruction
- 32. PDCA stuff

Here you will find all the links to useful webpages listed in this seminar booklet:



Andreas Heinzmann

Knowledge in the area of quality, certification, IRIS etc.

- One of three initiators of the IRIS standard and 1st President of the IRIS Group,
- responsible for the content and the successful launch of the IRIS certification system during the UNIFE general assembly in Geneva in 2006,
- from the beginning until today consistently involved in all IRIS revisions,
- one of the 5 core team members that were commissioned to draft the ISO/TS 22163- standard, numerous comments on the ISO DIS 22163 pre-standard,
- more than 1800 Manager trained and >75 companies (>120'000 employees) were successfully prepared for IRIS certification.

Professional career

- 1976 Masters degree (Dipl.-Ing.) in Electrical Engineering at TU Ilmenau,
- 1981 Institut für Regelungstechnik (development of sender & receiver for glasfiber optical systems),
- 1990 AEG-Westinghouse Berlin > AEG in Hennigsdorf, (Shanghai Metro, BR12X, VT 611/612),
- 1998 head of QHSE in Adtranz's "Light Rail Vehicles" Business Unit in Nuremberg,
- 2000 Bombardier (DWA) as General Manager for Quality & Customer Service,
- 2002 Senior Director Quality at Bombardier Transportation's headquarters,
- > 37 years professional experience > network of suppliers, operators, approval authorities and registrars, also in the automotive, aerospace and food industries,
- 2009 foundation of iCC-Rail GmbH, the global market leader in IRIS training, coaching and mentoring.

Training Objectives

- This training is developed especially for the Rail Industry and is based on current IRIS requirements (ISO 22163:2023 & IRIS Certification® Performance Assessment: 2023).
- It aims to provide you with all the necessary knowledge
 - 1. to reach the next qualification level (SILVER or GOLD) of your Rail Quality Management System (RQMS) in the most efficient way,
 - 2. to review and enhance the documents of your RQMS (flowcharts, instructions, etc.) for compliance with mandatory and optional requirements of **ISO 22163:2023**, and
 - 3. to refresh and expand your IRIS knowledge.
- Through this training you will...
 - receive an IRIS MANGER certificate, thus maintaining your IRIS training status for the next 3 years,
 - know where to get help if you have further questions, and
 - sleep well because the next audit can come.



Management of organizational knowledge and key roles (optional)



7.2 Competence

7.2.1 Competence — Supplemental

Process for competence management

HINT:

This mandatory process is presented in detail at flowchart in the previous seminar "Internal IRIS Auditor" and now, is skipped due to time constraints.



This process shall include: d) the requirements for training

NOTE Competence can include:

- technical skills such as product, process or project knowledge as well as application of software tools and/or techniques (e.g. quality assurance methods),
- 2. social skills (e.g. teamwork, communication, etc.), as well as
- 3. Individual skills (e.g. analytical thinking, business acumen etc.).



HINT: In various chapter of ISO/TS 22163 are specific competencies required (e.g., 8.1.2 Tender management, 8.1.3 Project management, 8.8 RAM/LCC, etc.). All these specific skills aren't explicitly referenced anymore, except knowledge and skills of internal auditors.

Chapter 7.2.1

To be applied to?

ALL employees, including the induction of temporary staff and new starters.

Core requirements:

- Identification of required technical, social as well as individual skills of all employees.*)
- Identify gaps between existing and required skills.
- Planning, organization, implementation and monitoring of actions to close potential gaps.

*) HINT: The required skills could be defined <u>per role</u> in TARGET-profiles. <u>Example</u>: with my Q departments I agreed on 11 profiles of the following <u>Roles</u>: Head of Q, Manager RQMS, Process Owner, PMQ, SWQA, EQA/Test Lab, SQA, QC/Incoming goods inspection, Measuring/Testing/Monitoring equipment, internal Auditor, welding engineer.

Principle: No employee performs work for which she/he is not qualified!

Chapter 7.2

example: skill matrix (technical skills)

7.5.3	7.5.3.3 Authorities shall be defined for persons who create, verify, approve, and update documented information.												
Authori well wit	ties can be linked very h skills	skills 2	sta	ff									
		Development - operating systems					r						
Explanation o	f four skill levels	MS DOS							H	\blacksquare			
	no requirements No experience and authority in this field	Wirwows Embedded		H	H	H		H	\blacksquare	\blacksquare	\blacksquare		
LEARNER: still works under supervision	Linux	H	H					H	₽	\square			
NO authorities yet		QNX	Ħ	Ħ	\square	H	H	H	Ħ	\blacksquare	\blacksquare		
	BASIC: is allowed to perform tasks autonomously	Development - programming											
	authority to create drafts	C		F	H			H			Ħ		
	ADVANCED												
	is able to guide/lead others authority to verify and approve in this field of expertise	C++		\blacksquare	Ħ		+		\square		\square		
	COACH Main responsible person	Perl		\blacksquare	H	H		H	\blacksquare	⊞	\blacksquare		
	Subject matter expert with leadership skills; can be used as a mentor	Assembler		H	H		H		Ħ	H	H		
	yellow defines the target	РНР								Ħ			
						-	-	-	Cł	napter	r 7.2		

Technical, social and individual skills

- 1. technical skills such as product, process or project knowledge as well as the application of software tools, methods (e.g. quality assurance methods), and
- 2. social skills (e.g. teamwork, communication, etc.) as well as
- 3. individual skills (e.g. analytical thinking, business acumen, etc.).

The higher a position's job grade, the more important become the social and individual skills.

Example: An operator in production must have very good technical skills to control machineries or carry out special processes (e.g. welding). Should he also have very good social skills, he could be promoted to team leader. If strong individual skills come on top, all doors are open to him. He could even become plant manager after additional studies. The higher he rises, the more product/process/project knowledge (expertise) he may lose. His tasks shift to other fields, such as team-, business- management, communication, motivation, strategic-, risk-based thinking, etc. Thus, each position has its own requirements, but always a mix of all 3 aspects, just with different focuses.

While technical skills are easier to define (see skills matrix), it is more difficult to define the required levels for social and individual skills. Here, the 4-level model (learner... coach) does not work..

Examples:	individual skills	social skills	
			13

Innovation Management (optional)

HINT: moved from Chapter 8.11 of ISO/TS 22163



Operational planning and control

8.1.1 Planning of the transfer of processes

HINT: The term OUTSOURCING isn't longer used in the standard.



processes

Applicable in case of:

- multi-sites organization when transferring a process from one site to another;
- single sites or multi-sites organizations when transferring processes to external organizations:
- the transfer requirements must be applied and controlled in case of changes too.

The implementation of this process shall be linked to

- business planning (4.1.1),
- business continuity (6.1.4),
- production and service provision (8.5),
- design and development of products and services (8.3) related decisions.

NOTE Processes not covered by 8.1.1.2 are covered under 8.4. (Purchasing EPPPS)

HINT:

- 4.1.1 refers to a strategic decision, e.g., to close a paint shop.
- 6.1.4 refers to a business continuity, e.g., in case of a flood, corrective equipment maintenance or a lack of capacity (temporary transfer of production)
- 8.5 refers to a temporary or permanent transfer in production, e.g., to due to cost savings;
- 8.3 refers to a transfer of design activities, e.g., due to a lack of internal competences.

Chapter 8.1.1

Operational planning and control

8.1.2 Tender management

Process for tender management

HINT:

This mandatory process is presented in detail at flowchart in the previous seminar "Internal IRIS Auditor" and now, is skipped due to time constraints.

HINT:

beside the fact that specific skills for bid-team members are cancelled, unfortunately, there are no change in this chapter. During the transition from IRIS Rev.02 to Rev.03 (2017), activities after submission of the offer were overseen and accidentally not transferred. Now, unfortunately, the opportunity to correct this mistake has been missed. Nevertheless, I recommend to consider these requirements (shown below in green) in the RQMS.



Operational planning and control

Are you aware about our Project Management master class? (info @ page 142)

8.1.3 Project management

Project management

DEFINITION

Project (3.1.2.18)

unique process undertaken to achieve an objective

Note 1 to entry: A project generally consists of a set of coordinated and controlled activities with start and finish dates, conforming to specific requirements, including the constraints of time, cost and resources.

Note 2 to entry: An individual project can form part of a larger project structure and generally has a defined start and finish date.

Note 3 to entry: In some projects the objectives and scope are updated, and the product or service characteristics defined progressively as the project proceeds.

Note 4 to entry: The output of a project can be one or several units of product or service.

Note 5 to entry: The project's organization is normally temporary and established for the lifetime of the project.

Note 6 to entry: The complexity of the interactions among project activities is not necessarily related to the project size.

[SOURCE: ISO 10006:2017, 3.3]

Gate-Methodology (3.1.2.6)

a project management practice to evaluate, at the end of each significant phase, the maturity of deliverables for moving to the next phase, with the proper risk evaluation and mitigation plans.

Note 1 to entry: The transition between two phases is formalized by control milestones.



Project management scopes

- Innovation Project
- 2 Project for the development of a new generic product or product family/platform
- **3** Typical Customer Project of Rail System Integrators: from tender till end of warranty



4 Projects of Rail Equipment Provider could be classified in categories like:



Project initiation & planning

DEFINITION

project management plan (3.1.2.21)

document specifying what is necessary to meet the objective(s) of the project

Note 1 to entry: A project management plan should include or refer to the project quality plan.

Note 2 to entry: The project management plan also includes or references other plans such as those relating to organizational structures, resources, schedule, budget, risk management, environmental management, health and safety management and security management, as appropriate.

[SOURCE: ISO 10006:2017, 3.5, modified — In note 1 to entry "project's quality plan" changed to "project quality management plan".]

project quality plan (3.1.2.25)

specification of the actions, responsibilities and associated resources to be applied to a

specific project

[SOURCE: ISO 10005:2018, 3.2, modified — Term changed from "quality plan" to "project quality management plan", "object" changed to "project".]

deliverable (3.1.4.3)

output for the scope of supply to fulfil defined requirements

EXAMPLES Product, services, user manual, training manual, maintenance manual, test reports, test equipment, training, spare and support parts.

(8.1.3.2) PMP (harmonized between all stakeholder) shall include or refer to:

- deliverables per phase (e.g. contractual deliverables for customers or documented information of the design outputs intended for product approval) including:
 - identification of deliverables to be approved by the customer (e.g. customer product acceptance points) or statutory and regulatory authorities, where required;
 - external providers' deliverables (e.g. documents, material, services);
 - customer deliverables, such as customer properties, as applicable;

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Example CDRL:

Chapter 8.1.3

Project initiation & planning

Process to manage projects

HINT:

This mandatory process is presented in detail at a 2-page-flowchart in the previous seminar "Internal IRIS Auditor" and now, is skipped due to time constraints.

DEFINITION

project organization (3.1.2.22) temporary structure that includes project roles, responsibilities and levels of authority and boundaries that need to be defined and communicated to all interested parties of the project. [SOURCE: ISO 10006:2017, 3.6] (8.1.3.9) Establish, implement and maintain a register including a cost and benefit analysis of risks and opportunities,

- involve functional line managers in risk reviews;
- consider operational + integration maturity levels of the products agreed with the customer as inputs for risk assessment;
- manage opportunities for cost savings (to balance losses) or cost enhancements (to increase margin), especially in order to recover the project budget deteriorations.

(8.1.3.3) Define scope of work & subdivide work into work packages (WBS), assign responsibilities to work package owners and verify work packages.

Establish project specific mandates (for each work package)

Example: work packages:



(8.1.3.4) Define sequences of activities, estimate resources and durations of activities (work packages), establish schedule, identify critical path and provide input to the master production schedule

(8.1.3.5) Take over project budget from tender calculation (budget baseline), assign budgets to work packages and implement cost account structure.

Network and Conventions



Exercise 2: Have you ever built a house?

- On the right you see a table with activities that are required to build a house.
- Together, please prepare a net plan to represent the sequence of work.
- Please define the "earliest" and "latest" completion date.



activities	duration in weeks
architects planning	5
decoration	2
land clearance	1
purchase of materials	1
building a hovel	1
assembly of doors	2
building the house shell	4
building the base plate	2
assembly of window	1
find construction company	2
installation of heating	2
painting	1
laying tiles	4
laying parquet	2
assembly of stairs	1
electrical installation	6
building the roof	2
inside plastering	3

Time Management

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Budget allocation



Project execution & closure

(8.1.3.11) Project review management

perform regular project reviews to monitor project progress with the attendance of the core team members include:

- project performance (actual situation vs. planned situation) based on PIs (requirements, time, costs including actual and estimated cost at completion),
- the forecast (e.g., time, estimated cost at completion),
- the actual risks & opportunities, including status of related actions,
- tracking of open issues and actions from previous reviews,

In case of an imminent deviation to the project objectives, identify and implement appropriate counter measures *with a common methodology* to avoid or mitigate any impact on customer, the organization and/or other interested parties.

NOTE Project reviews are intended to monitor the progress of the complete project. Project phase reviews (see 8.1.3.1) are intended to check if a project phase can be closed and a next project phase can begin.

Project Change Management

- 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 as defined by the organization (8.1.3.3)
- The project organization shall not change the schedule regarding the customer delivery dates unless a change request has been timely addressed to the customer. (8.1.3.4)
- The project organization shall not increase the project budget unless authorized as defined by the organization by the organization. (8.1.3.5)



Chapter 8.1.3

Cost calculation

- Project costs are direct costs and shall be planned, captured and tracked during the entire project life cycle.
- Follow the standard structure of the work packages (WBS). Set for each work package a costs account.
- For each cost account, specify the respective cost elements (hours, material costs, ODC, etc.)



Budget- Variance analyze



Variance 1 is the current deviation of the actually consumed resources. But beware! The current degree of completion could be below the planned due to delay...

Year	h	cum h	h	cum h	h	cum h
Aug	30	30	15	15		
Sep	20	50	35	50		
Oct	40	90	32	82		
Nov	70	160	60	142		
Dec	80	240	70	212		
Jan	100	340	60	272		
Feb	50	390	50	322		
Mar	20	410	20	342		342
Apr	10	420			20	362
May	5	425			40	402
Jun	20	445			50	452
Jul	30	475			30	482
Aug	80	555			100	582
Sep	100	655			100	682

Chapter 8.1.3

Time - Analysis of Variances



OPERATIONS



Application of requirements management



CASE A: design and development of new products or services meeting market expectations prior to tender (e.g. platform, product family);

Requirements management may start with an idea generation in the market strategy phase and finishes with the release of a new product/technology and/or new manufacturing process (product status: ready for sale).

<u>Remark:</u> CASE A can also include maybe few performance & integration + commercial requirements.

CASE B: customer specific application in tender management (e.g. submission of tenders, acceptance of contracts or orders), project execution (e.g. acceptance of changes to contracts or orders) and during change control in various cases such as transfer, requirements management, design, purchasing and production.

Requirements management could start in the tender phase and finish when all performance requirements are met (e.g. RAM/LCC). All kind of requirements (functional, non-functional, performance, integration and commercial) must be in scope and evaluated.

Annex B: subordinate concept of requirements for products and services



Operational- and Integration Maturity

Quality Engineering - maturity model

Operational- and Integration Maturity

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Error report:

Clause 3.1.3.7: operational maturity

What went wrong?

3.1.3.7 operational maturity: degree of fulfilment of the technical requirements (3.1.3.10) of a product or service.

Consequences:

Integration maturity (as it was used in ISO/TS 22163) is merged with other things and contradicts the spirit/intention of Annex B. It was an optional requirement and most of the European System Integrators committed to introduce this approach in 2016 (when the VDB Guide "Quality Engineering during design phase of rail vehicles and rail vehicle systems" was published by DB AG in collaboration with VDB and Prof. Rudolph <u>download</u>). At this time, it was a big step forward. Now ISO 22163 is pointing in the wrong direction.

Explanation:

Annex B provides many differentiations between technical-, non-technical-, functional-, non-functional- etc. requirements. In total it contains 7 different requirement categories. But for what purpose all this effort? Probably because each of the categories is different in its verification and validation needs. For example, functional requirements will be much more reviewed in the earlier design stages, while performance requirements needs to be validation tested prior to release, sometimes very late during the first commissioning (e.g. LRV's will run test trials on the tracks of the city to validate curve radii or entry heights). In particular, integration requirements such as mounting spaces or signal interfaces, must be tested e.g. during a first system installation. Here in this context, the matter of maturity is used to plan the necessary extend of verification and validation activities by comparing previous proven and new products regarding its operation as well as interfaces between systems und subordinate subsystems regarding its integration. Its a kind of risk-based thinking. The more mature a product is, the less verification- and validation- activities needs to be conducted. If it is un-mature or brand new, it needs maybe all verification and validation activities (QA-methods) applicable in the design stages. Hence, the current concept of operational maturity and integration maturity is useful, and I wished it would stay. If not, Annex B and the split into functional, and non-functional requirements are useless ballast, since on one hand we differentiate 7 classes of requirements, on the other hand we merge everything to one operational maturity only (as a response to technical requirements), and hence, preventing so a selective planning of QA-methods for verifying or validating the various requirement categories, based on maturity. I add 3 pages explaining more details on this subject matter.

Suggestion for improvement:

3.1.3.7 operational maturity: degree of fulfilment of **functional** (3.1.3.2), **performance** (3.1.3.8) **and other non-functional requirements** of a product or service.

3.1.3.(new) Integration maturity: degree of fulfilment of integration requirements (3.1.3.5) of a product or service.

Annex B: Subordinate concept of requirements for products and services

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Exercise 4: QA-Methods

Second question: Where would you place the QA methods in this phase model?

0 Market- strategy	Product Developm, 2 Bi	d Banning	4 Application Design	5 _{Realization}	6 Warranty					
Third question: even more specific, in this design stages?										
Requirements Analysis	Concept Design	Preliminary Design	Detailed Design	Finale Desig	n					
Stages for design an	d development (sucl	<mark>n as shown in this exa</mark> i	nple) shall be doo	cumented (8.3.2.	.1). Chapter 8.2					

Planning of QA methods for product, (manufacturing) process &. purchased parts approvals (PPPA)

re	equired evidences for the approval (Mountainbike)	load-bearing parts	Frame	Handlebars	Saddle	Front suspension fork	Rear suspension fork	Rolling Stock	Wheels	Drive	Pedals	sprocket	Chain	Circuit	Brakes	Control elements	Transmission	Brake elements	Attachments	Lighting	Handlebar grips	Bell	Fastenings (pre- equipped)	Design
Engineering	Products design review functional tests accompanying development Product FMEA Material testing Calculations (FEA, compressive strength, mechanical strength) Integration tests (First System Installation) EMV tests Vibration/shock/vibration tests Temperature tests Fatigue strength tests FCIL material classifications			21																		••••		e
Methods	Production drawings, production parts lists, Work- and testing instructions/reports, linspection planning Incoming goods inspections Declaration of Conformity (3.1 Certificate of the manufacturer) Marking of customer property (e.g. injection tools, moulds) Operation readiness review, pre-manufacturing review Archiving of verification documents and configuration data Purchased parts							•																
Supplier	Product FMEA Material testing customer FAI FAI with final customer Integration tests (First System Installation) Inspection of the first delivery (marking, packaging technology, serial/batch numbers/labels, completeness of the delivery documents, contents of the 3.1 certificate) Archiving of verification documents and configuration data																							hapter 8.2

The "high" school for ADVANCED

Requirements traceability matrix

Tool e.g.: IBM Engineering Requirements Management DOORS Next

https://www.ibm.com/en-en/products/requirements-management-doors-next/pricing

	2														
Creative Design Applicability	2 No						_								
Design Manual	Consult Eng Manual						Cvc	tom							
Lessona Learnad	Consult Englidential														
Lessons Learned	Consult Knowledge Wiki														
FUNCTIONS	DESCRIPTION	PARAMETER			RANCE		applicable	Validation	annlicable	validation					
. choriente	DECOMM HON		units	- +		Verification Mode	drawing	Mode	procedures	reports					
Weather proof															
	Seals shall be air tight at max operating speed	70	mph	0	10	Mock Up	docID xyz	Type testing	docID xyz	Report #:					
Precludes water and show inflitration	Shall pass 30 minute watertest at indicated pressure	45	psi	0	Х	Mock Up	docID xyz	Type testing	docID xyz	Report #:					
Resistance															
Pesists static loads	Hinge & door attachments to resist passenger weight	350 vertical @	lbe	×	×	Decign Review	docID xyz	Type testing	docID xvz	Peport #:					
Resists static loads	Thinge & door attachments to resist passenger weight	edge	105	^	^	Design Review	docid xyz	Type testing	docid xyz	Report #.					
Movement															
Rotates up to 100 degres	Door stop needs to sustain impact by door	5	mph	Х	Х	3-D Simulation	docID xyz	Type testing	docID xyz	Report #:					
Closes by itself	Closing speed	1	ft/s	0	0.5	Test	docID xyz	Type testing	docID xyz	Report #:					
Installation															
Installs easily (time)	Meet PP/CM time as per Design to Cost (DtC) file	0	min	х	0	Design Review	docID xyz	Initial assembly	docID xyz	Report #:					
	Meet Installation (MVT) time as per Design to Cost DtC file	30	min	х	0	Design Review	docID xyz	Initial assembly	docID xyz	Report #:					
Interfaces															
Provides sufficient clear opening	Provide same as existing cars as a minimum	27.5	in	0	Х	3-D Simulation	docID xyz	Installation test	docID xyz	Report #:					
Environment															
Reduces noise coming from outside	Noise reduction necessary to maintain 72 dB inside the car	10	dB	0	х	Labtest (design phase)	docID xyz	Vehicle type test	docID xyz	Report #:					
Prevents thermal loss	K factor	0.24	х	х	х	Materialtests	docID xyz	Vehicle type test	docID xyz						
General															
Aesthetically pleasant / Integrated with surroundings	Finish as per existing cars (inside & outside)	#4 horizontal	х	х	х	Customer	docID xyz	customer- acceptance	docID xyz	Report #:					
Meet Budget	Meet costs as per Design to Cost (DtC) file	15	U\$	Х	0	DtC File	docID xyz	Recalculation	docID xyz	Report #:					
Meet Weight	Meet weight budget	25	lbs	х	х	weight-management file	docID xyz	Weighing	docID xyz	Weighing log#:					

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Chapter 8.2

Requirements management

8.2 **Requirements for products** Determine following requirements: functional-, non-functional requirements-, RAMS/LCC – and services requirements, obsolescence requirements, critical HINT: new mandatory requirements were upgraded (in product characteristics plus applicable statutory and previous ISO/TS 222163 optional requirements) regulatory requirements & those considered necessary by the organization; Process to manage • requirements regarding configuration requirements management and change control (8.1.4), identification, traceability (8.3.3.1) and records retention (7.5.3) (green topics are not required in ISO 22163, but utmost important); • experience from similar tender- / project-activities; requirements resulting from market analysis; requirements regarding end of product life • production and routine testing requirements, including special processes, so far as the production facilities are known at this stage (8.3.3.1); • preservation of products (8.3.3.1) • standards or codes of practice that the organization has committed to implement • potential consequences of failure due to the nature of the products and services. • production abilities (e.g., smallest machine tolerances, floor widths, ceiling loads, etc.) Chapter 8.2

Critical characteristics

Source: Dr.-Ing. Alexander Schloske

Besonderemerkmale -- Systematisch ermitteln und Durchgängig Behandeln

🜌 Fraunhofer

DEFINITION

Critical characteristics are **product characteristics** and/or **process characteristics** that have an impact on the **functional safety** (operational and usability safety), the **compliance with regulatory requirements**, the **form**, **fit**, and **function**, the **performance** or the **further processing of the product**. [see TS 16949, VDA 4.3, VDA 6.1]

Chapter 8.2

Fundamentals: Critical characteristics

Obligation to exercise due care in the product development process to ensure technically relevant functionalities

- obligation to exercise due care in the product development process:
 - design and calculation
 - testing and verification
 - managing errors in operation
 - documentation and record keeping
- obligation to exercise due care in the production process:
 - production planning and manufacturing

Source: Dr.-Ing. Alexander Schloske

- effective test planning and testing
- managing errors in production
- documentation and record keeping

Development

Critical characteristics and their legal relevance

critical characteristics	legal relevance
Safety relevance: product safety or safety-related consequences (severity = 10 in the FMEA)	Criminal law: criminal liability of employees in the event of fault
 Homologation relevance: regulatory and statutory requirem. at the time of product approval (severity = 9 in the FMEA) 	Public law: authorities of approval bodies (restrictions, delivery stop, warning, product recall)
Functional relevance: functional and non-functional requirements (severity = 5 8 in the FMEA)	Civil law: warranty (repair, rescission, reduction, liquid damages)

Source: Dr.-Ing. Alexander Schloske, adopted for rail sector by A.Heinzmann

Chapter 8.2

Critical characteristics and their legal relevance

critical characteristics

- Safety relevance: product safety or safety-related consequences (severity = 10 in the FMEA)
- Homologation relevance: regulatory and statutory requirem. at the time of product approval (severity = 9 in the FMEA)
- Functional relevance: functional and non-functional requirements (severity = 5 .. 8 in the FMEA)

issues

- Could prosecution charge us due to injuries to life and limb if we deviate from the characteristic?
- Could an authority order a delivery stop or a product recall if there is a deviation from the characteristic??
- Could we incur increased warranty costs in the event of deviations from the characteristic?

Source: Dr.-Ing. Alexander Schloske, adopted for rail sector by A.Heinzmann

The "high" school for ADVANCED

Example: functions and characteristics

Source: Dr.-Ing. Alexander Schloske

Chapter 8.2

Example: functions and characteristics

Systematic analysis and consistent consideration of the critical characteristics (example pen)

Development

- Definition of the inner diameter of the cap and the outer diameter of the base body as CFC
- Tolerance analysis for cap and base body
- Creation of boundary samples (cap with minimum inner diameter and base body with maximum outer diameter)
- Plug test with 1000 cycles with boundary samples and subsequent evaluation of the pull-off force

Production

 Monitoring of inner and outer diameters (moldbased process, all cavities)

Source: Dr.-Ing. Alexander Schloske

Development

Production

Critical characteristics

Documentation and archiving of critical characteristics as a records of proof in the event of a claim

Development:

documentation in risk analyses and on drawings (1)

Ø23,5mm SC)
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Production- and test planning:

documentation of control-, test- and reaction methods in test plans and work instructions

Production:

recording and documentation of the critical characteristics (measured values)

Records Keeping:

- documentation, archiving and traceability of results
 - requirement specifications for CC = 15 years after end of production
 - quality records of CC = 15 Jahre after production

Error report: 8.2.2.1.3: Records Retention of requirements	udy			
What went wrong? 8.2.2.1.3: The organization shall retain documented information in relation to 8.2.2 a) to b) and 8.2.2.1.1 a) to b) and, if considered, 8.2.2.1.2 a) to c).				
Consequences: Fatal error! The obligation to retain documentation on critical characteristics was overlooked. In a product liability case, one cannot rely on exculpatory evidence. There is a 15-year retention obligation!				
Explanation :				
There is no requirement to archive records for: c) Obsolescence requirements, as applicable (e.g. information from the market, external suppliers, regulations); nor for d) critical characteristics as defined by the organization and/or the customer.				
Special characteristics contain safety and/or function critical requirements and are therefore extremely important evidence in case of product liability! If you only follow ISO 22163, you still do not meet the legal requirements!				
Suggestion for improvement: 8.2.2.1.3: The organization shall retain documented information in relation to 8.2.2 a) to b) and 8.2.2.1.1 a) to d) considered, 8.2.2.1.2 a) to c).	and, if			

The "high" school for ADVANCED

Application of risk filters

Application of risk filters

Source: Dr.-Ing. Alexander Schloske

Systematic analysis and consistent consideration of critical characteristics with FMEA

The FMEA methodology is perfectly suited for the **systematic and consistent analysis** of critical characteristics:

- Product-FMEA
 - identification of the critical characteristics
 - functionally correct design of the critical characteristics (objective: lowest probability of occurrence)
- Process-FMEA
 - assessment of the probability of occurrence in production
 - planning of actions for safe prevention and/or detection in production (objective green area in the A*E matrix).

Source: Dr.-Ing. Alexander Schloske

Chapter 8.2

Failure mode and effect analysis (FMEA)

structure systemstructure process

assign functions and characteristics
 create function/characteristic network

derive malfunctions and error characteristics
 establish failure network (hypotheses)

define preventive actionsdefine fault detection and fault reaction

plan optimization
 check effectiveness

Source: Dr.-Ing. Alexander Schloske

For your notes

Exercise 5: critical characteristics of a cable

Consistent analysis of product characteristics Product FMEA - Process FMEA - Control plan

- 1. dielectric strength,
- 2. insulation class
- 3. ampacity
- 4. tensile strength
- 5. shielding (HF properties)
- 6. pollutant-free / fire properties (e.g. halogen-free)
- 7. UV properties
- 8. aging
 -
- Now, for these characteristics, actions for failure prevention, -detection and reaction must be defined in a product-FMEA. *What could this be?*
- A process-FMEA is linked to this. How could this be continued in the production processes?
- and the inspection plan must be created too. What could play a role in this matter?

For IRIS Experts and their motivation, do you know our seminar **"IRIS Coach"**?

Objective: the participation in this seminar supposes that you already have a comprehensive basic IRIS knowledge and that you hold either an IRIS Internal Auditoror IRIS Manager degree. It aims to equip you with all the necessary knowledge enabling you:

- · to be a competent contract and contact person for certification bodies,
- to successfully lead and train internal auditors in your company,
- to verify business management documents (flowcharts, process instructions, etc.) for compliance with ISO 22163 norm, and
- to be a first point of contact for all process owners and your entire company because you are the most competent person regarding the IRIS certification system in all technical IRIS matters.

Who else should motivate you if not yourself?

Read sample end

This is where this reading sample ends. Not all of the 266 pages are shown. Other pages we continue with al lot of detailed explanations, notes and examples, as well as many exercises and case studies for more in-depth study.

Our customer satisfaction is on average 95%!

Our global services

IRIS LEARNING

- as classroom, online or hybrid training,
- provided in house or in public seminars

Our learning concept

Much more details (such as the schedule, seminar contents, participation fees, venues, etc.) about the "HIGH SCHOOL" seminars offered by the IRIS Academy can be found on our website https://www.cc-rail.info/en/under IRIS ACADEMY.

The BEST for the BEST: seminar offers

-	IRISACADEMY The "HIGH" SCHOOL invites:	1.849-00-UF	Burging	entrope and	usterite Benatic	tonson
1	IRIS TOP Management Awareness	TOP Management, members of 1st line	2 hour	proof of attendance	exclusively offered in-house only	overview, asuming of responsibility, commitment for improvement, provision of resources
2	The HIGH school for Internal IRIS Auditors IRIS basics	all process owner, internal auditors	5 day	certificate internal IRIS Auditor	to efficiently understand the entire IRIS certification system	ISO 22163 requirements &. IRIS certification rules, mandatory and selected optional requirements, all mandatory processes
3	The HIGH school IRIS Refresher & extention Rev. 4 Update	all process owner, internal auditors	2,5 day	certificate IRIS Manager	to renew expired certificates + for all who want to achieve more	Focus on changes between IRIS Rev.03 and Rev.04, as well as the implementation of the new "SILVER & GOLD" requirements.
4	IRIS Coach (highest skill level)	heads of QM, IRIS administrators	2 day	certificate IRIS Coach	IRIS auditor or IRIS Manager qualification must be available	seminar is currently suspended- will be offered in 2024
	The HIGH school for Supplier Performance Manager (+SQA)	SQA, LEAD Buyer, internal auditors	4 day	certificate Supplier Performance Manager	goes far beyond the IRIS requirements, only for professionals	procurement strategies, supplier management, improvements in delivery services
	The HIGH school for RAWLCC Manager	RAWLCC experts, internal auditors	4 day	certificate RAWLCC Manager	shorter than a university study, but just as good for practitioners	IEC 62278, EN 50126-1, CLC/TR 50126-3, maintenance strategies, FRACAS, Life Cycle Cost
	The HIGH school for IRIS Project Manager (+ PQM)	Project Manager, PQM, Project core team	4 day	certificate IRIS Project Manager	direct preparation for the iapm- certification	understand project management correctly and apply it resonably in smaller businesses
	QM Special Engineer	executives for succession		diploma QM Special Engineer	please see <u>https://www.cc-rail.info/en/qm-special-engineer/</u>	

More transparency isn't possible ...

Much more details (such as the schedule, seminar contents, participation fees, venues, etc.) about the "HIGH SCHOOL" seminars offered by the IRIS Academy can be found on our website https://www.cc-rail.info/en/ under IRIS ACADEMY.

IRIS CONSULTING

(coaching &. mentoring to achieve IRIS certification usually provided @site but works well online in between too)

Milestones to achieve IRIS Certification

@site or online?

To understand customer needs or to evaluate actual situation it is indispensable to visit the customer at its site. Also, to get commitment, to activate and engage stakeholder, most of the workshops must be conducted f2f. However, there are often needs and opportunities in between to save travel costs/time through online meetings.

Online workshops

- based on @site activities, incl. agreed planning, NDA, schedules, work-packages, fair budgets or fixed package prices,
- freely scalable scopes depending on customer needs,
- taking leadership and introducing a well-structured approach to manage the improvement project,
- professional support providing world-class standards and proven solutions of the rail industry, including

 drafts of all IRIS topics (flowcharts, procedures, templates), (2) tailor-made solutions and (3) final
 reviews, as necessary.

(for more detailed info, please visit <u>https://www.cc-rail.info/en/coaching</u>/)

IMPROVEMENT

(topics can be flexibly defined and clustered dependent on business needs)

IRIS TOP MANAGEMENT AWARENESS MEETING

Objectives:

- 1. to introduce myself to the management team and provide updates on system requirements for IRIS certification (at executive level),
- 2. to strengthen the understanding of the roles and responsibilities of TOP managers,
- to discuss the approach to IRIS implementation (to understand how long it will take, how much it will cost, and what resources are required to understand existing gaps, close them, achieve certification, and then sustain it),
- 4. to motivate TOP management to establish a strong RQMS, and finally
- 5. to obtain TOP management commitment to support IRIS implementation.

target group: Executive management

methodology: ZOOM meeting preparation, presentations, questions/answers/discussion.

<u>duration</u>: 2 hour (1,5 hour for presentation, 1/2 hour Q&A)

<u>info-booklet</u> (72 slides) ready to print (pdf)

in-house Workshops to prepare for SILVER/GOLD

- 1. Risk Management and Quality Deficiency Cost
- 2. Configuration-& Change Management and Traceability
- 3. Project Management
- 4. Requirements Management
- 5. Process Landscape and process structure
- 6. External provided products, processes and services
- 7. Customer complaint- and repair process (e.g., during warranty period)
- 8. The HIGH SCHOOL for Process Owner (2 days: seminar, incl. workshop)

Starting on page 4 of this newsletter, you will find descriptions of these 8 workshops.

https://www.cc-rail.info/wpcontent/uploads/2017/09/N-E-W-S-L-E-T-T-E-R-September-en-rev01.pdf

in-house workshops to prepare for SILVER/GOLD

Bibliography

References from ISO 9001:2015

ISO 9004	Quality management — Quality of an organization — Guidance to achieve sustained success
ISO 10002	Quality management — Customer satisfaction — Guidelines for complaints handling in organizations
ISO 10004	Quality management — Customer satisfaction — Guidelines for monitoring and measuring
ISO 10005	Quality management — Guidelines for quality plans
ISO 10006	Quality management systems — Guidelines for quality management in projects
ISO 10007	Quality management — Guidelines for configuration management
ISO 10017	Quality management — Guidance on statistical techniques for ISO 9001:2015
ISO 19011	Guidelines for auditing management systems

References specific to the railway sector

CENELEC CLC/TS 5070	1 Railway applications — Cybersecurity
DIN 6701	Adhesive bonding of railway vehicles and parts
EN 15085	Railway applications - Welding of railway vehicles and components - Part 1: General
EN 15380-2	Railway applications — Designation system for railway vehicles — Part 2: Product groups
EN 50126	Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)
EN 62402	Obsolescence management
Guideline 1: 2020	KEY PERFORMANCE INDICATORS (KPIs)
Guideline 2: 2022	FIRST ARTICLE INSPECTION
Guideline 3: 2020	MAINTENANCE
Guideline 4: 2022	RAMS/LCC
Guideline 5: 2022	OBSOLESZENCE MANAGEMENT
Guideline 6: 2020	SPECIAL PROCESSES
Guideline 7: 2021	PROBLEM SOLVING
Guideline 8: 2022	CONFIGURATION- &: CHANGE MANAGEMENT
Guideline 9: 2021	Small and medium sized enterprises (SMEs)
Guideline 10: 2021	PROJECT MANAGEMENT
CC-Rail Guideline 1: 202	2 RISK AND OPPORTUNITY MANAGEMENT
IEC 60050-192	International electrotechnical vocabulary — Part 192: Dependability
IEC 60050-821	International Electrotechnical Vocabulary — Part 821: Signalling and security apparatus for railways
IEC 61508	Requirements and Guidance in the use of mathematical and logical techniques for establishing exact properties of software and its documentation

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IEC 62278	Railway Applications Specification and Demonstration of Reliability — Availability, Maintainability and Safety (RAMS)
IEC 62279	Railway applications — Communication, signalling and processing systems — Software for railway control and protection systems
IEC 62425	Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling
IRQB	IRIS Certification® Conformity Assessment 2020
ISO 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
RIC: 2004	Railway Industry Collaboration Project - the beginning of the norm
UNIFE: 2006	1st Commitment for the Rail Industry
UNIFE: 2012	2nd Commitment for the Rail Industry
UNIFE: 2013	Commitment for the supply chain
VDB-Guideline	Quality Engineering during Design phase of Rail Vehicles and Rail Vehicle Systems

Other references

ISO 10012	Measurement management systems — Requirements for measurement processes and measuring equipment
ISO 13053-2	Quantitative methods in process improvement — Six Sigma — Part 2: Tools and techniques
ISO 15663	Petroleum, petrochemical and natural gas industries — Life cycle costing
ISO 16047	Fasteners - Torque/clamp force testing
ISO 21500	Project, programme and portfolio management - Context and concepts
ISO 22301	Security and resilience — Business continuity management systems — Requirements
ISO 26000	Guidance on social responsibility
ISO/IEC 27000	Information technology — Security techniques — Information security management systems — Overview and vocabulary
EN 13306	Maintenance — Maintenance terminology
iapm GUIDE 2.0	GUIDELINE FOR THE CERTIFICATION OF PROJECT MANAGERS
IPC-A-610	Acceptability of Electronic Assemblies
IPC-A-620	Requirements and Acceptance for Cable and Wire Harness Assemblies

Please rip out and fill in

Criteria	Preparation and focus of the training	Duration of the training	Value of the training for you	Instructors competence and behaviour
5	Excellent preparation; correct focus, effective planning & communication	Very effective use of time, involving all necessary trainees	Significant improvement potential identified; many new ideas & opportunities	Very competent; very fair and rational, able to bring new understanding
4	Good preparation; correct focus, good planning and communication	Right duration, good use of time and involved necessary people	Useful improvement potential identified; new opportunities and ideas for action	Fully competent; fair & rational approach, able to explain the IRIS Certification System in detail
3	Acceptable; I was informed and understood focus and training plan	Acceptable duration for a fair fee	Confirmed current understanding of the IRIS Certification System; some new opportunities identified	Acceptable; professional & with a good understanding of the IRIS Certification System
2	Needs improved; training focus not right for me, communication poor	Too short for a training	Limited value; did not add to my understanding	Needs improved; not sufficiently experienced for this Training
1	Very poor preparation; wrong focus, ineffective communication	Unacceptable; significantly too short or too long	No value; waste of time, leading into wrong direction	Incompetent; prejudiced, unfair, not rational, no respect for participants

Please rate each criteria from 1 to 5 in accordance with your personal preception of the training

Please rip out and fill in

What did you like most this seminar?	What should I improve in the next training?	
Would you recommend the Training to other sites: please circle		
Not at all = 1 2 3 4 5 6 7 8	9 10 = Almost certainly	